#15

PATENT
Docket No. AM100151-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Childers, et al.

Serial No. 09/706,683 **Examiner:** E. Bernhardt

Filed: November 6, 2000 **Art Unit:** 1624

Confirmation No: 8281

Title: BRANCHED ADAMANTYL AND NORADMANTYL ARYL- AND ARALKYLPIPERAZINES WITH SEROTTININ 5-HT1A ACTIVITY

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EU733074668US addressed to the Commissioner for Patents, Washington, DC 20231.

September 12, 2002
Date

Paula L. Dickey
Paula L. Dickey

REPLY TO EXAMINER'S ANSWER PURSUANT TO 37 C.F.R. §1.193

Commissioner for Patents
Washington, DC 20231

Sir:

This is a reply to the Examiner's Answer mailed on July 12, 2002 for the above-identified application. This reply is being submitted in accordance with 37 C.F.R. §1.193(b)(1) and thus entry is respectfully requested in accordance with 37 C.F.R. §1.193. This reply brief is being submitted in triplicate; copies of the cases cited herein are enclosed.

Applicants respectfully submit that there is good cause for the Board to consider this reply brief as it is directed to those areas of the Examiner's Answer where the Examiner has elaborated more fully or clarified previous arguments that Applicants have not had the opportunity to fully respond to. For example, the Examiner provides more factual arguments

in the Section 112 rejection why it is believed that Applicants' specification is not enabled for failure of Applicants to provide guidance as to which compounds are agonists versus antagonists. The Examiner also provides more factual arguments as to why it is believed Applicants' examples do not support enablement of the full scope of the claims. With respect to the rejection under Section 103, the Examiner has clarified that Cliffe is being used only as a secondary reference and has provided more specific arguments as to why it is believed the synthesis of Applicants' compounds would be enabled by Abou-Gharbia and Cliffe. Thus, Applicants respectfully submit that there is good cause for the Board to consider this reply brief and accordingly request consideration of this reply.

Applicants submit that the Examiner has erroneously maintained the Grounds of Rejection for the reasons that follow as well as the reasons previously set forth in Applicants' appeal brief filed on April 16, 2002, which for the sake of brevity is hereby incorporated by reference in its entirety.

A) Rejection Under Section 112, first paragraph of Claims 1,2,16, 27 to 30 Should Be Vacated

The Examiner has stated that the rejection under Section 112, first paragraph is based on an "insufficient disclosure of how to use for scope claimed...". The Examiner appears to base this rejection on the following arguments:

a) the specification does not provide enough guidance to teach which compounds are agonists, antagonists or mixed profile at the 5HT1A receptor site; and

b) given the "unpredictability" of this art area as evidenced by Applicants' own test data, the compounds tested in the Example section are not representative of the full scope of Claims 1, 2, 16, 27 to 30.

The Examiner also places heavy reliance on a 1966 CCPA case, *In re Surrey*, 151 USPQ 724 (CCPA 1966), which Applicants submit is distinguishable from the facts of this application for the reasons set forth below.

Applicants submit that the Examiner is requiring far more than what Section 112, first paragraph requires. Enablement under Section 112, first paragraph requires that the specification teach those skilled in the art how to make and use the invention without undue experimentation. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 224 USPQ 409, 413 (Fed. Cir. 1984). The issue of whether one skilled in the art must engage in undue

experimentation to make and use the claimed invention is *decided on the facts of each case. Ex parte* Obukowicz 27 USPQ 2d 1063, 1067 (Bd. Pat. Appl. & Int'f 1992). That some experimentation is necessary, or that some embodiments encompassed within the claims are inoperable, does not preclude enablement. *Atlas Powder Co.*, at 414. Additionally, complex experimentation is not undue if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture microcarriers, 221 USPQ 1165, 1174 (U.S. Int'l Trade Comm. 1983).*

With these standards in mind, Applicants submit that there is *ample* disclosure in the specification to teach one skilled in the art to use the full scope of Applicants' claimed invention. For example, the compounds encompassed by Claims 1, 2, 16, and 27 to 30 are all taught in Applicants' application as having affinity for the 5HT1A receptor site (*see e.g.,* application page 3, lines 28 to 30). Test methods are provided in the application for determining whether a compound has affinity at the 5HT1A receptor, and further, test methods are provided for determining whether the compound is an agonist or antagonist at the 5HT1A receptor site (*see e.g.,* specification, page 18, line 30 to page 19, line 26). Applicants also teach that compounds having affinity at the 5HT1A receptor site have a variety of "end" uses as disclosed in the background section of Applicants' application. For example, utilities are disclosed for 5HT1A agonists and partial agonists (page 1, line 36 to page 3, line 16) and 5HT1A antagonists (page 3, lines 18 to 24). Thus, Applicants have disclosed that all the compounds of the present invention have affinity at the 5HT1A site and are thus useful as agents in mammals to treat a variety of conditions, independent of whether the compound is an agonist, partial agonist or antagonist.

In response to the Examiner's argument that Applicants do not provide guidance as to which compounds are agonists versus antagonists, Section 112, first paragraph, at least with respect to compound claims (e.g., claims 1 and 2 of the present application), does not mandate such a detailed disclosure. In fact, the opposite is true, in that not all compounds claimed need to be useful for *every* utility disclosed in an application (*see e.g., Ex parte Hozumi,* 3 USPQ2d 1059, 1060-1061 (Bd. Pat. App. & Int'f 1987); *Ex parte Cole,* 223 USPQ 94, 95 (Bd. Pat. App. & Int'f 1983), or have the *same degree* of utility (*see e.g. In re Gardner,* 177 USPQ 396, 398 (CCPA 1973). Thus, all that is required is that Applicants disclose some use or uses that *in total* covers all the subject matter. Applicants have done this in teaching that the compounds claimed have affinity for the 5HT1A receptor and

disclosing end uses for compounds having affinity for this receptor. Applicants further submit that it is within the realm of reasonable experimentation (i.e., not undue), as Section 112, first paragraph permits, for one skilled in the art to determine which compounds are agonists versus antagonists according to the test methods disclosed in Applicants' specification, or other methods known to those skilled in the art, and based on this determine which "end" uses would be most appropriate. For these reasons, Applicants respectfully submit that the Examiner has erred in requiring that Applicants' specification teach which compounds are agonists versus antagonists in order to comply with the "how to use" enablement portion of Section 112, first paragraph.

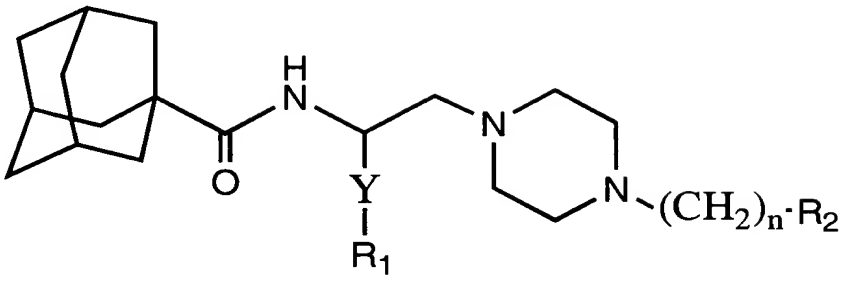
With respect to Claims 16 and 27 to 30, directed to a method of treating stroke, it is noted that both 5HT1A agonists and antagonists have been identified in the literature before the filing of Applicants' application as being useful for treating stroke (see e.g., WO95/11891, page 4, lines 30 to 34 and claim 19, and Applicants' specification page 1, line 35 to page 2, line 33). Thus, Applicants respectfully submit that in view of this, both 5HT1A agonists and antagonists appear to be effective for treating stroke and as such the Examiner's requirement that Applicants teach which compounds are agonists versus antagonists is not required under Section 112, first paragraph. Moreover, even if only agonists or only antagonists were useful for treating stroke, Applicants respectfully submit that it would be within the realm of reasonable experimentation (i.e., not undue), as Section 112 permits, for one skilled in the art to determine, according to the test methods herein or other methods known to those skilled in the art, whether the compound in question is an agonist or antagonist. Accordingly, Applicants respectfully submit that Claims 16 and 27 to 30 fully meet the requirements of Section 112, first paragraph.

With respect to the Examiner's arguments that Applicants have not provided enough of working examples to demonstrate that the full scope of the compounds covered in claims 1, 2, 16, 27 to 30 are useful, it is emphasized that the Examiner has the initial burden of providing evidence to show that there are reasons to doubt Applicants' statements in the specification that the compounds claimed are useful as having affinity for the 5HT1A receptor. *See e.g., Fiers v. Sugano,* 25 USPQ2d 1601, 1607 (Fed. Cir. 1993) (a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as in compliance with the enabling*

requirement of the first paragraph of Section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support). *See also, e.g., In re Brana* 34 USPQ2d 1437, 1441 (Fed Cir. 1995).

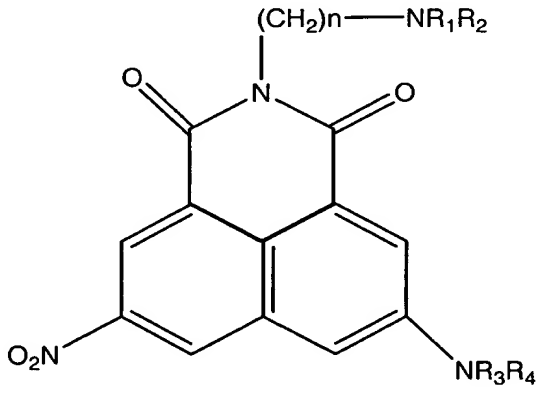
In the present situation, the Examiner has not presented sufficient evidence to place in doubt Applicants' statements in the specification concerning utility to overcome this initial burden. Accordingly, Applicants have no obligation to come forward with rebuttal evidence. The Examiner points to the fact that Applicants' own data is unpredictable in that some compounds are agonists while others are antagonists. The Examiner also notes that there is a 30-fold difference in the 5HT1A binding affinity data. Both of these points are irrelevant with respect to the sufficiency of Applicants' teachings in the specification of how to use the compounds of the present invention in accordance with Section 112, first paragraph. In this regard, it is noted that *all* compounds tested had affinity for the 5HT1A receptor (see the specification, page 19, Table 1). The fact that some of the compounds are agonists, while others are antagonists is irrelevant to the question of enablement as previously discussed. Moreover, one skilled in the art would recognize that the variability of the data in Table 1 is not unusual and is to be expected in such an art area. For example, see the 5HT1A binding affinity data in U.S. Patent No. 5,254,552 to Abou-Gharbia, column 17, ranging from 1 nM to 67 nM. Thus, the Examiner's conclusion that the data in Applicants' specification provides evidence that the utility of the full scope of compounds claimed is questionable is completely without merit.

As an alternative, the Examiner states, without any factual proof, that the compounds as diverse as the rings, rings systems embraced have not been shown as a class as having the minimum requisite activity needed to practice the invention and there is no reasonable basis for assuming that the myriad of compound embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically nonequivalent and there is no basis in the prior art for assuming the same (*see* Examiner's Answer, page 5, last 8 lines of page). Applicants disagree that the compounds embraced by the claims are so structurally dissimilar, because all the compounds claimed possess the following structure:



where R_1 and R_2 are aromatic carbocyclic or heterocyclic compounds that are selected from a) aryl (e.g., aromatic carbocyclic compounds such as phenyl or napthyl), b) monocyclic heteroaryl of 5 to 6 ring atoms or c) a bicyclic heteroaryl having a phenyl ring fused to a monocyclic heteroaryl ring as defined previously. Moreover, the substituents for R_1 and R_2 in Applicants claims are not so diverse, in connection with compounds having affinity for the 5HT1A receptor, that one of ordinary skill in the art would question the utility. Applicants submit that a review of the related art would support this position.

It is noted that the facts of this case are quite similar to the facts before the CAFC in *In re Brana*, 34 USPQ 2d 1437 (Fed. Cir. 1995), where the CAFC reversed a Board decision that maintained an Examiner's rejection of the claims under Section 112, first paragraph for failure of applicants to prove that the claimed compounds were useful. In *In re Brana*, the compounds under question were disclosed in the specification as being antitumor agents and had the following structure:



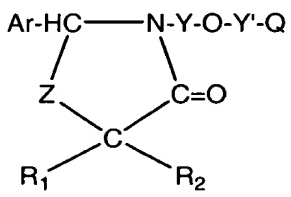
where R_1 and R_2 were independently selected from H, C_1-C_6 alkyl, C_1-C_6 hydroxyalkyl, pyrrolidinyl, morpholino, piperidinyl, piperacinyl and R_3 and R_4 were each

independently selected from H, C_1-C_6 alkyl, C_1-C_6 acyl, C_2-C_7 alkoxycarbonyl, ureyl, amino carbonyl, C_2-C_7 alkylaminocarbonyl. *Id.* at 1437-38.

The CAFC held that the Board failed to provide any evidence that the compounds claimed were not antitumor agents, and the PTO had thus failed to meet its initial burden to raise a question as to the utility stated in Applicants' specification. *Id.* at 1441. Moreover, the court went further to note that even if the PTO had met its initial burden, Applicants had provided test data to show that *several* compounds within the scope of the claim showed antitumor activity, and this would be sufficient *alone* to overcome any questions concerning the asserted utility. *Id.* at 1441-1442.

Just like in *In re Brana*, the Examiner has provided no concrete evidence to suggest that the compounds encompassed within the present invention are not useful. The Examiner merely relies on the fact that the art area of chemical compounds used to treat mammals can be unpredictable. While unpredictability can be common in the chemical art area under certain circumstances, Applicants have provided data showing that at least seven compounds of the present invention have affinity for the 5HT1A receptor. Moreover, although changes in substituents of a compound can sometimes alter the behavior of a compound in the human body, there is no evidence to suggest on record that one skilled in the art would not believe the utility stated in Applicants' specification. For these reasons Applicants respectfully submit that the claims are enabled by the specification in accordance with Section 112, first paragraph.

The Examiner has relied heavily on the case, *In re Surrey*, 151 USPQ 725 (CCPA 1966), in support of the position that Applicants' Claims 2, 16, and 27 to 30 are not enabled under Section 112, first paragraph. Applicants respectfully submit that the facts of this application are completely different, and therefore the holding of *In re Surrey* is not relevant here. It is noted that in *In re Surrey*, it was asserted that Applicants had failed to disclose how to use the full scope of compounds claimed by the following formula.



where Ar was various recited aromatic carbocyclic and heterocyclic moieties, Z was S, SO, or SO_2, and Q was a lower alkyl or a substituted or unsubstituted phenyl. *Id.* at 725. The CCPA in this case held that the claims were not enabled under Section 112, first paragraph for failure of Applicants to exemplify any heterocyclic substituents for Ar ***and*** *for the failure of Applicants to provide in the specification or in Appellants' brief any unequivocal statement that compound,* ***other than those actually tested,*** *are anticonvulsants or psychomotor stimulants.* *Id.* at 730.

Applicants, in contrast to the facts of *In re Surrey*, have stated unequivocally in the specification that the compounds claimed have affinity for the 5HT1A receptor and have taught how this affinity is useful for treating certain conditions in mammals. Further, Applicants have provided test data to exemplify both carbocyclic aromatic substituents (phenyl) as well as a heterocyclic aromatic susbtituent (pyrimidinyl – e.g., Ex. 3, Ex. 4). However, more importantly to these factual differences, it is submitted that the disclosure required in 1966 (more than 30 years ago) to satisfy the "how to use" portion of Section 112, first paragraph would have been quite different due to the state of art at that time in view of the genus of compounds being claimed. (*See e.g., In re Brana* at 1442, where court discusses that prior art can support an asserted utility in an application). Thus, it is improper for the Examiner to blindly take, without a more thorough analysis, a case decided over 30 years ago, and insist, based on this case, more working examples should be provided in Applicants' specification, simply because the CCPA held that for a particular genus of compounds being claimed in *In re Surrey*, more working examples should have been provided in view of the state of the art at that time. For these reasons, *In re Surrey*, cited by the Examiner, is inapplicable to the present situation. Applicants' specification provides ample disclosure to teach one skilled in the art to use the full scope of Claims 1, 2, 16 and 27 to 30.

In view of the above remarks, Applicants respectfully submit that the Examiner's reasons for rejection of Claims 1, 2, 16, and 27 to 30 under Section 112, first paragraph have no merit and the rejection of these Claims under Section 112, first paragraph should be vacated by the Board.

B. Rejection of Claims 1 to 3 Are Not Obvious Under Section 103 over Abou-Gharbia in view of Cliffe

The Examiner has maintained the rejection of Claims 1 to 3 under 35 U.S.C. §103(a) over Abou-Gharbia in view of Cliffe. In maintaining this rejection, the Examiner has improperly singled out 2 working examples in Abou-Gharbia, to the exclusion of the entire teachings of the patent, and improperly modified them using Cliffe as a secondary reference, without any regard to a) what each of the patents teach *as a whole* and b) the lack of teaching or suggestion in either of the references to make such a modification of the primary patent. This type of hindsight reconstruction is clearly improper as previously stated in Applicants' appeal brief. Thus, Applicants submit that the Examiner has not established a prima facie case of obviousness for the reasons set forth in Applicants' appeal brief and for the reasons discussed below.

Applicants emphasize that in order to properly combine references to support an obviousness rejection under Section 103, there must be some disclosure or suggestion within at least one of the references or knowledge generally available to one of ordinary skill in the art to support the combination. *Ashland Oil Inc. v. Delta Resins and Refractories, Inc. et al.*, 227 USPQ 657, 667 (Fed. Cir. 1985). Citing references which merely indicate that isolated elements and/or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed element would have been obvious. *Ex parte Hiyamizu,* 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Int'f 1988). Rather, in considering whether a claim is obvious in view of a reference or combination of references, the teachings of each of the references as *a whole* must be considered in view of the claims *as a whole* being examined. *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 8 USPQ 2d 1468, 1475 (Fed. Cir. 1998). Thus, the Examiner's statement that because one can, in an *anticipation* rejection, rely on a single compound in a reference to support such a rejection, that one can also rely on a single compound disclosed in a reference in an obviousness rejection, *to the exclusion of the teachings of the entire disclosure,* is clearly improper as it ignores the teachings of the reference *as a whole.* In an obviousness determination, the entire disclosure of a reference must be considered, *not just the working examples.*

The Examiner urges that Applicants are ignoring the two closest compounds in Abou-Gharbia. Applicants respectfully point out that the Examiner is ignoring the full teachings of Abou-Gharbia and Cliffe *as a whole* including the preferences taught therein. For example,

Applicants ask where is the motivation in Abou-Gharbia or Cliffe for one of ordinary skill in the art to:

a) in Abou-Gharbia, select R_1 to be adamantly or a noradmantyl moiety when the indolyl, and benzofuran moieties are also specifically listed or exemplified (see Abou-Gharbia, col. 2, lines 6 to 64); and

b) in Abou-Gharbia, select m equal to two, when m equal to three is equally preferred (see Abou-Gharbia, col. 2, lines 20 to 64); and

c) in Cliffe select out *just* the CR_2R_3 moiety to modify Abou-Gharbia, *to the exclusion of a plurality of other possible modifications of Abou-Gharbia with Cliffe,* such as placing the R substituent of Cliffe on the piperazinyl moiety of Abou-Gharbia, substituting X of Cliffe for R_1 of Abou-Gharbia, or substituting X of Cliffe for the $-NR_3CO(CH_2)_nR_1$ moiety of Abou Gharbia; and

d) in Abou-Gharbia, placing the CR_2R_3 moiety of Cliffe in just the place of *one* of the $(CH_2)_m$ moieties *and* locating this replacement in the position *adjacent to* the NR_3 moiety; and

e) in Cliffe, setting R_3 to an aryl or aryl (lower) alkyl to the exclusion of an alkyl group.

Applicants submit that there is absolutely no motivation in either Cliffe or Abou-Gharbia to "pick and choose" as the Examiner has done above. Clearly, the Examiner has used Applicants' claims as a "template" to improperly combine Abou-Gharbia and Cliffe. This is of course legally improper. See *In re Wesslau,* 147 USPQ 391, 393 (CCPA 1965).

Moreover, in response to the Examiner picking Example 37 out of 60 examples in Cliffe, Applicants submit that one of ordinary skill in the art would have absolutely no motivation to do this based on Cliffe or Abou Gharbia. For example, the performance data in Cliffe of Example 37 for 5HT1A receptor activity, relative to the other examples tested, would not stand out to one of ordinary skill in the art as other examples appear to have better activity (see e.g., column 7, lines 50 to 68). Thus, there is simply no disclosure or suggestion in either of Cliffe or Abou-Gharbia to combine these patents in the manner the Examiner has done. In fact, some of the modifications needed, as discussed above, would clearly teach away from the preferences taught in these two references. Thus, Claims 1 to 3 would not have been obvious to one of ordinary skill in the art over Abou-Gharbia in view of Cliffe.

With respect to the Examiner's arguments that Abou-Garbia and Cliffe disclose synthesis methods that would be useful for synthesizing compounds of the present invention, it is emphasized that as neither of these patents alone or in any proper combination disclose or suggest Applicants' compounds, these patents cannot contain enabling disclosures for making the compounds of Applicants invention.

For these reasons and for the reasons stated in Applicants' appeal brief filed on April 16, 2002, it is respectfully submitted that the Examiner has erred in maintaining the rejection of Claims 1 to 3 under 35 U.S.C. §103(a) over Abou-Gharbia in view of Cliffe. Accordingly, the Board is respectfully requested to vacate this rejection under Section 103.

CONCLUSION

Applicants request that in view of Applicants' appeal brief and the remarks made herein that all grounds of rejection and objections in the above identified application be vacated by the Board.

Respectfully submitted,

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Date: September 12, 2002

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must conclude that agreement has been reached on all material terms." *Brock*, 841 F.2d at 154.

[2] Here, the district court summarily concluded that "[t]he parties . . . entered into a stipulation and agreement in open Court . . . ." We believe this finding of fact was clearly erroneous. Notably absent from its order is any discussion of whether the parties agreed as to Thermoscan's secondary identifier obligations. If the district court had engaged in such an analysis, it would have recognized that the source of the disagreement was the district court's own language. The parties' collective conduct following the February 26, 1999 hearing confirms that there was ambiguity in the district court's recitation of the disputed term.

As previously noted, the district court set forth the understanding of the parties as follows: "[A]ll marketing in the future of the Thermoscan thermometer shall include the name 'Braun' *prominently displayed* either in the advertising or on the package. And *I'm not saying that it has to be equal size, bigger or smaller, but just visible* . . ." (Emphasis added.) Both sides indicated in open court that they agreed with the district court's outline of the settlement terms, but their subsequent dispute makes clear that each heard only what it wanted to hear. TSI honed in on the words "prominently displayed" and naturally expected them to be in the written agreement. Thermoscan, on the other hand, fixated on the words "just visible" and equally expected them to be the controlling standard.

These reasonable differences in interpretation manifested themselves in heated debate during the drafting process, a situation that highlights the disagreement between the parties and the obvious materiality of the disputed term. *See, United States v. Orr Constr. Co.*, 560 F.2d 765, 770 (7th Cir. 1977) ("[T]he record shows that the parties consistently clashed over the meaning of [a clause in their tentative agreement] during the course of their negotiations following the exchange of proposals, indicating that they never had reached a true agreement.").

The basic problem is that, at least as it relates to size, the terms "prominently displayed" and "just visible" are inherently incompatible. Yet the district court used both terms in successive sentences. Although either party could have, and perhaps should have, pointed out this inconsistency to the district court, there is no basis to blame one side any more than the other for failing to do so. *See Flower City Painting Contractors, Inc. v. Gumina Constr. Co.*, 591 F.2d 162, 165 (2d Cir. 1979) ("[W]e cannot say that either party acted so unreasonably as to justify construing the ambiguity in the contract against it.").

We recognize that a trade name can be "prominently displayed" by means other than size, such as by font, placement, color, or relief. But Thermoscan objected to any language that included the term "prominently displayed," despite its explicit mention by the district court as a key provision of the proposed settlement. The end result was simply no objective manifestation of a "meeting of the minds" on this material term of the settlement. *See United Paperworkers Int'l Union v. Champion Int'l Corp.*, 908 F.2d 1252, 1258 (5th Cir. 1990) ("In determining whether there was a meeting of the minds, the parties' objective, rather than subjective, intent governs."); *see also Local Motion, Inc. v. Niescher*, 105 F.3d 1278, 1280 (9th Cir. 1997) ("The presence of an ambiguous material term may indicate that no meeting of the minds occurred when the document was signed."). Because the root source of the ambiguity was the district court's own inconsistent language, we believe that it was an abuse of discretion for the court to impose Thermoscan's version of the settlement upon TSI.

C. The question of whether the district court erred when it dismissed TSI's suit with prejudice is rendered moot

Because we are remanding this case for further proceedings, the issue of whether the district court erred when it dismissed TSI's claims with prejudice is rendered moot.

III. CONCLUSION

For all of the reasons stated above, we *REVERSE* the judgment of the district court and *REMAND* the case for a ruling on Thermoscan's motion for summary judgment and, if necessary, for a trial on the merits.

U.S. Court of Appeals
Federal Circuit

In re Kotzab

No. 99-1231

Decided June 30, 2000

PATENTS

1. Patentability/Validity — Obviousness — Combining references (§115.0905)

Evidence does not support finding that combination of prior art references teaches

use of single temperature sensor to control plurality of flow control valves, as in method for injection molding plastic articles claimed in patent in suit, since rejection of claims in re-examination was based on prior art statements that "one system" may be used to control several valves, and that single sensor may be used to provide "the temperature measurement at a selected part of the machine," but there is not substantial evidence to show that "one system" is same as "one sensor," or that skilled artisan, confronted with problem noted by inventor of patent in suit and two statements in prior art, would have been motivated to control plurality of valves in multiple-zone setting with only one temperature sensor.

2. Patentability/Validity — Obviousness — Combining references (§115.0905)

Although test for establishing implicit teaching, motivation, or suggestion in prior art is what combination of prior art statements would have suggested to those of ordinary skill, such statements must be considered in context of teaching of entire reference, and cannot be viewed in abstract, and rejection of claims cannot be predicated on mere identification in prior art reference of individual components of claimed limitations; rather, particular findings must be made as to reason skilled artisan, with no knowledge of claimed invention, would have selected these components for combination in manner claimed.

3. Patentability/Validity — Obviousness — Combining references (§115.0905)

Identification of prior art statements that, in abstract, appear to suggest claimed limitation does not establish prima facie case of obviousness without finding as to specific understanding or principle within knowledge of skilled artisan that would have motivated one with no knowledge of invention at issue to make combination in manner claimed.

Particular patents — Chemical — Injection molding

5,427,720, Kotzab, method for mold temperature control, decision holding invention unpatentable reversed.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Werner Kotzab appeals from final decision, in Reexamination No. 90/004,441, holding claims 1-10 of patent in suit unpatentable for obviousness under 35 U.S.C. §103(a). Reversed.

Robert F.I. Conte, Thomas Eugene Smith, and James B. Conte, of Lee, Mann, Smith, McWilliams, Sweeney & Ohlson, Chicago, Ill., for appellant.

Mark Nagumo, associate solicitor, Albin F. Drost, acting solicitor, John M. Whealan, acting deputy solicitor, and Stephen Walsh, associate solicitor, U.S. Patent and Trademark Office, Arlington, Va., for appellee.

Before Lourie, Gajarsa, and Linn, circuit judges.

Linn, J.

DECISION

Werner Kotzab appeals from the final decision of the Board of Patent Appeals and Interferences ("Board") holding claims 1-10 in reexamination number 90/004,441 unpatentable for obviousness under 35 U.S.C. § 103(a). *See Ex Parte Kotzab*, Paper No. 17 (BPAI July 15, 1998). This case was submitted for our decision following oral argument on April 4, 2000. Because certain of the Board's key factual findings relating to its obviousness analysis are not supported by substantial evidence, and because the Board erred in concluding that the claims would have been obvious as a matter of law, we reverse.

BACKGROUND

A. The Invention

The invention involves an injection molding method for forming plastic articles. In such methods, the temperature of the mold must be controlled so that the plastic can harden uniformly throughout the mold. Kotzab was confronted with the problem of providing optimal temperature control for an injection molding method to ensure the quality of the final product on the one hand, and achieving optimally short molding cycle times on the other hand. He arrived at a

otzab appeals from final deci-
examination No. 90/004,441,
ms 1-10 of patent in suit un-
or obviousness under 35 U.S.C.
versed.

Conte, Thomas Eugene Smith,
B. Conte, of Lee, Mann, Smith,
ns, Sweeney & Ohlson, Chica-
r appellant.

mo, associate solicitor, Albin F.
ing solicitor, John M. Whealan,
puty solicitor, and Stephen
ociate solicitor, U.S. Patent and
k Office, Arlington, Va., for

ie, Gajarsa, and Linn, circuit

DECISION

Kotzab appeals from the final
he Board of Patent Appeals and
s ("Board") holding claims 1-10
ition number 90/004,441 unpa-
obviousness under 35 U.S.C. §
Ex Parte Kotzab, Paper No. 17
15, 1998). This case was submit-
lecision following oral argument
2000. Because certain of the
factual findings relating to its
analysis are not supported by
vidence, and because the Board
cluding that the claims would
bvious as a matter of law, we

BACKGROUND

A. The Invention

tion involves an injection mold-
for forming plastic articles. In
ls, the temperature of the mold
ntrolled so that the plastic can
rmly throughout the mold. Kot-
nfronted with the problem of
timal temperature control for an
lding method to ensure the qual-
al product on the one hand, and
ptimally short molding cycle
e other hand. He arrived at a

solution which is embodied in claim 1 of the reexamination as follows:

1. An improved method of controlling the temperature of an injection mold by pressure feeding molding material into a mold recess of an injection mold by an extruder, curing the material in the mold, and removing molded material from the mold, said pressure feeding, curing, and removing being a molding cycle of recurring molding cycles and said recurring molding cycles having at least a first molding cycle and a second molding cycle,

comparing a preset nominal temperature to an actual temperature measured by at least one temperature sensor during said first molding cycle and said second molding cycle and supplying an amount of a temperature controlling medium to the first molding cycle and the second molding cycle, said amount of temperature controlling medium being dependent on the deviation between the actual temperature measured and the desired preset nominal temperature, the improvement comprising:

controlling, via a single sensor, a plurality of flow control valves for the temperature controlling medium to provide impulse temperature control medium to the first and second molding cycles,

determining empirically or by calculation a quantitative spacial distribution of temperature controlling medium needed to obtain said desired preset nominal temperature during at least the first molding cycle and the second molding cycle and determining empirically or by calculation the conduits needed to be utilized to obtain the desired preset nominal temperature during at least the first molding cycle and the second molding cycle,

comparing said desired preset nominal temperature to said actual temperature, at least once during the first molding cycle and the second molding cycle at a certain point in time being the same for each said molding cycle, such that said comparison made during said first cycle is synchronized with said comparison made during said second subsequent molding cycle, and said plurality of flow control valves are triggered during each said cycle to provide said impulse control medium, and said triggering being dependent on the deviation of temperature determined for each said comparison and also being dependent on a stored profile of said quantitative spacial distribution of the temperature controlling medium.

J.A. at 18-19.

Claim 3, which depends from claim 1, adds the following further limitation: "wherein a flow measuring turbine is associated with each flow control valve to detect the actual flow in each cycle and wherein a proportioning of a cooling or heating medium is effected in dependence on a comparison of a nominal flow to the actual flow." *Id.* at 19.

Claim 10, which depends from claim 3, additionally provides that "the rotation of said measuring turbine is transferred into pulses, so that the nominal flow [of the temperature controlling medium] can be fixed by the presetting of a corresponding number of pulses." *Id.* at 20.

B. The Reexamination Proceeding

U.S. Patent 5,427,720 ("the '720 patent") issued to Kotzab on June 27, 1995. A third party filed a request for reexamination on November 4, 1996. The reexamination was granted and assigned control no. 90/004,441. The amended claims were finally rejected by the Examiner, and Kotzab appealed the rejections to the Board. On July 15, 1998, the Board affirmed the Examiner's rejection of the claims for essentially the reasons expressed in the Examiner's Answer. The Board did, however, provide its own additional comments primarily for emphasis.

Specifically, the Board agreed with the Examiner that WO 92/08598 ("Evans") discloses a process of controlling the temperature of an injection mold by using a sensor to control the pulsing of a temperature control medium through the mold. Moreover, the Board found, as explained by the Examiner, that Evans discloses in a less preferred embodiment, using only one temperature measurement to control the coolant pulses rather than an average temperature measurement. *See* Evans application, p.6, ll. 17-23.

In addition, the Board found that Evans discloses that "the optimum timing of the cooling flow can be selected in accordance with the known temperature of the mould." *Id.* at ll. 6-8. Furthermore, the Board found that a prior art promotional article discloses that manipulation of the geometry and layout of the cooling segment provides for the greatest improvement in molding cycle. *See* Horst Wieder, *Understanding the pulse modulated mold temperature control meth-*

od, (CITO Products, Inc., WI.) 1987, at p. 1, col. 2, ll. 13-16. And, the Board determined that a May 1984 prior art article indicates that it was known to establish a cooling regime before the mold is produced, and that the determination of the cooling regime includes the number and location of the cooling conduits, as well as the volume of the coolant flow. Thus, the Board concluded that the evidence of record indicates that it was known in the art to utilize empirical data to design the mold and the distribution of cooling channels in that mold. In view of the foregoing, the Board found that the empirical determination of the necessary spacial distribution of the length of the cooling pulses needed for delivering the appropriate coolant is disclosed by Evans or was known at the time the invention was made. Consequently, the Board affirmed the Examiner's rejection of claims 1, 2, and 4-9 under 35 U.S.C. § 103(a) as being unpatentable over Evans.

The Board made additional findings related to claims 3 and 10 in determining that they were also unpatentable under 35 U.S.C. § 103(a) over Evans in view of certain secondary references.

Kotzab filed a request for reconsideration, which the Board denied on November 24, 1998. In that decision, the Board reiterated agreement with the Examiner that it would have been obvious for one of ordinary skill in the art to utilize only one temperature measurement to control the coolant pulses in light of the Evans disclosure. Kotzab timely appealed the Board's decision to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994).

DISCUSSION

A. Standard of Review

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *See* 35 U.S.C. § 103(a) (Supp. III 1997); *In re Dembiczak*, 175 F.3d 994, 998, 50 USPQ2d 1614, 1616 (Fed. Cir. 1999). The ultimate determination of whether an invention would have been obvious under 35 U.S.C. § 103(a) is a legal conclusion based on underlying findings of fact. *See Dembiczak*, 175 F.3d at 998, 50 USPQ2d at 1616. We review the Board's ultimate determination of obviousness de novo. *See id.* However, we review the Board's underlying factual findings for substantial evidence. *See In re Gartside*, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000).

Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence. *See id.* at 1312, 53 USPQ2d at 1773 (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229-30 (1938)). In reviewing the record for substantial evidence, we must take into account evidence that both justifies and detracts from the factual determinations. *See id.* (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951)). We note that the possibility of drawing two inconsistent conclusions from the evidence does not prevent the Board's findings from being supported by substantial evidence. *See id.* Indeed, if a reasonable mind might accept the evidence as adequate to support the factual conclusions drawn by the Board, then we must uphold the Board's determination. *See id.*

B. Analysis

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *See Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). Thus, every element of a claimed invention may often be found in the prior art. *See id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *See In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Even when obviousness is based on a single

r substantial evidence. *See* 03 F.3d 1305, 1316, 53 76 (Fed. Cir. 2000).
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. Analysis

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prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *See B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996).

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. *See Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. *See WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. *See In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981) (and cases cited therein). Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. *See Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. Broad conclusory statements standing alone are not "evidence." *Id.*

Kotzab's primary argument that the Board erred in holding claims 1-10 unpatentable under 35 U.S.C. § 103(a) over Evans, or Evans in view of secondary references, is that Evans does not teach or suggest the use of a single temperature sensor to control a plurality of flow control valves. We agree.

As noted previously, the Board adopted the Examiner's reasoning in upholding the rejection of the claims and added further comments. None of the Board's comments relate to the issue of Evans teaching or suggesting the use of one *sensor* to control a number of valves regulating coolant flow to the mold. Thus, we look to the Examiner's reasons for finding this limitation to be expressly taught or suggested in Evans.

The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."

[1] But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. Evans uses the word "signal" to refer to the response generated by the measured temperature that controls the valves for coolant flow. Finally, the word "system" is used in Evans to refer to the overall temperature control system that is responsible for the valve timing for coolant flow to increase or decrease the temperature of the mold. Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."

As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

[2] The United States Patent and Trademark Office argues that because Evans teaches that a single sensor may be used to provide "the temperature measurement at a selected part of the machine," it necessarily follows that the Evans "system" discussed later may have a single sensor—and that single sensor may control more than one valve. *See id.* at p. 6, ll. 21-23; p. 19, ll. 6-8. While the test for establishing an implicit teaching, motivation, or suggestion is what the combination of these two statements of Evans would have suggested to those of ordinary skill in the art, the two statements cannot be viewed in the abstract. Rather, they must be considered in the context of the teaching of the entire reference. Further, a rejection cannot be predicated on the mere identification in Evans of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

We do not take issue with the argument that Evans suggests the concept of using the historic temperature obtained by one temperature measurement to control coolant pulses. *See id.* at p. 5, ll. 14-22; p. 6, ll. 17-23. However, there is not substantial evidence of record to extrapolate this teaching to the multiple zone system described later in Evans. *See id.* at p. 18, l. 22 to p. 19, l. 8. In the

multiple zone system, Evans describes the use of a temperature sensor and an associated flow control valve in each zone. At most, the combined teachings suggest that the historic temperature of a mold zone may be measured by one sensor, and as part of a multiple zone system where multiple valves are controlled, that one sensor measurement can be used to control the valve for that zone. Thus, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that where there are a plurality of control valves in a multiple zone setting, only one temperature sensor provides the control for a plurality of valves.

Moreover, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support implicitly the conclusion that a skilled artisan confronted with (1) the problem noted by Kotzab, i.e., providing optimal temperature control for an injection molding method to ensure the quality of the final product on the one hand, and achieving optimally short molding cycle times on the other hand, and (2) the two statements in Evans, would have been motivated to control a plurality of valves in a multiple zone setting with only one temperature sensor.

[3] In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper *prima facie* case of obviousness in rejecting claims 1, 2, and 4-9 under 35 U.S.C. § 103(a) over Evans. Moreover, because the rejections of claims 3 and 10 rely upon the foregoing, we also conclude that the Board did not make out a proper *prima facie* case of obviousness in rejecting those claims under 35 U.S.C. § 103(a).

CONCLUSION

For the above reasons, we conclude that there is not substantial evidence to support the Board's finding of fact that Evans expressly teaches that "one sensor" may be used to control a plurality of valves, and there is not substantial evidence of record, either expressly or implicitly, to modify the teachings of Evans to obtain a system in which one sensor controls a plurality of valves. Accordingly, we

REVERSE.

National Arbitration Forum

General Media Communications Inc. v. JMR Creations

No. FA0004000094387

Decided June 1, 2000

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Infringement; conflicts between marks — Willful (§335.11)

REMEDIES

Non-monetary and injunctive — Equitable relief — Seizure (§505.0703)

Internet domain name "Penthouse.net," registered to respondent, will be transferred to complainant in administrative proceeding for determination of rights in name, since it is nearly identical and confusingly similar to several trademarks and domain names in which complainant has rights, and in which respondent has no rights or legitimate interests, since respondent registered and acquired "Penthouse.net" primarily for purpose of selling or otherwise transferring it to complainant, or to compete with complainant, and since respondent therefore has registered and used this domain name in bad faith.

Administrative proceeding initiated by complainant General Media Communications Inc. against respondent JMR Creations for determination of rights in Internet domain name "Penthouse.net," pursuant to Uniform Domain Name Dispute Resolution Policy of Internet Corporation for Assigned Names and Numbers. Decision in favor of complainant.

Floyd A. Mandell, Orrin S. Shifrin, and Joni S. Jacobsen, of Katten Muchin Zavis, Chicago, Ill., for complainant.

aminer, and the need under the facts of this case for a careful interpretation of those proceedings by one of ordinary skill in the art, explanatory testimony could aid the trial court (if it had doubt) in ascertaining the scope of the [claim].

Under the circumstances of this case, summary judgment should not have been granted.

3. *"Uniform Outer Diameter"*

MedComp continues to adhere to its interpretation of the phrase "uniform outer diameter" in claim 7 as an alternative basis for affirming the judgment below. MedComp contends that because this limitation was added during prosecution, Howes is estopped from claiming a catheter with a tapered distal tip, wherefore its catheter does not infringe. The district court rejected this argument as a basis for granting summary judgment, holding instead that it was reasonable to include tapered catheters within the scope of claim 7.

If one thing is clear from the prosecution history of the patent, it is that Howes added the limitation of a uniform outer diameter at the distal end of the catheter tube only to distinguish the catheter in *Bielinksi*, U.S. Patent No. 3,437,088, which had protuberances along its length. Some additional gloss was placed on this language by Howes' patent attorney in distinguishing the Cournand catheter during reissue, but Cournand was distinguished on a number of grounds. Significantly, the non-uniformity in the Cournand catheter body is not at its tip — it begins halfway along the length of the catheter body. At most, Howes' argument to the examiner can be taken, as surrendering from claim coverage a catheter with size changes along its insertion length, not at its tip.

C. *Other Errors*

It is a truism that this court reviews judgments, not opinions, *see, e.g., Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 781, 218 USPQ 673, 677 (Fed. Cir. 1983), but the district court's July 22, 1985, summary judgment order contains several misstatements of law which should not be left without comment.

The district court in several places appears to confuse claim allowance with infringement of third party patents, stating that "Howes was compelled to amend his patent application to avoid infringing prior art patents" and that the Howes patent was allowed because "small but significant differences are enough to prevent infringement." In discussing the doctrine of equivalents, the court seems equally confused in its observation that although the differences between MedComp's catheter and Howes catheter were not great, "small changes have been enough to distinguish new catheters from prior art."

It is impossible to deduce whether these obvious misstatements contributed to the erroneous judgment below. *Cf, Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984) ("language in an opinion . . . may indicate that harmful errors of law produced an erroneous conclusion"). They do, however betray a lack of familiarity with certain fundamentals of patent law which should be remedied on remand.

CONCLUSION

[1] We hold, therefore, that the district court erred as a matter of law in construing claim 7 as limited to Fig. 3 of the Howes patent based on its interpretation of the words "joined" and "freely" as contained therein. In doing so, the district court also failed to recognize genuine issues of material fact surrounding the reissue of the patent which make summary judgment inappropriate in this case. The judgment of non-infringement of claim 7 by MedComp and AHS is *vacated* and the case is *remanded* for further consideration consistent with this opinion.

VACATED AND REMANDED

Court of Appeals, Federal Circuit

In re Geiger*

No. 86-1103

Decided April 1, 1987

PATENTS

1. Patentability/validity — Obviousness — Evidence of (§115.0903)

Obviousness cannot be established by combining teachings of prior art to produce

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* This opinion issued as an unpublished opinion on December 11, 1986. On request of counsel for appellant, it is now being reissued as a published opinion.

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ATED AND REMANDED

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urt f Appeals, Federal Circuit

In re Geiger*

No. 86-1103

Decided April 1, 1987

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December 11, 1986. On request of counsel
pellant, it is now being reissued as a pub-
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claimed inventi n, absent some teaching, suggestion, or incentive supporting combination, and thus, although it might have been obvious to one skilled in art to try various combinations of teachings of three prior art references to achieve claimed method, such evidence does not establish prima facie case of obviousness.

Particular Patents — C rrosi n inhibit r

Geiger, application No. 373,903, for method of inhibiting scale formation on and corrosion of metallic parts in cooling water systems, Claims 43-63, and 65-67, not obvious.

Appeal from United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent of Gary E. Geiger, application, Serial No. 373,903, from affirmation of rejection of claims, applicant appeals. Reversed; Newman, Circuit Judge, concurring with opinion.

Bruce E. Peacock, Trevose, Pa., for appellant.

Robert D. Edmonds, associate solicitor (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief), for appellee.

Before Skelton, Senior Circuit Judge, and Newman and Archer, Circuit Judges.

Archer, Circuit Judge.

This is an appeal from a decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board), Appeal No. 606-09, affirming the examiner's rejection of all remaining claims, 43-63 and 65-67, in appellant's patent application, Serial Number 373,903 ('903), under 35 U.S.C. §103. We reverse.

OPINION

Background

The '903 application, filed on May 3, 1982, is directed to a method of inhibiting scale formation on and corrosion of metallic parts in cooling water systems by use of compositions containing (1) a sulfonated styrene/maleic anhydride (SSMA) copolymer, (2) a water soluble zinc compound, and (3) an organo-phosphorus acid compound or water soluble salt thereof.

In its decision dated February 7, 1986, the board affirmed the examiner's rejections under 35 U.S.C. § 103, finding that the claimed subject matter would have been obvious in view of various combinations of references, but with reliance primarily upon U.S. Patent No. 4,209,398 issued to Ii, et al. (Ii), U.S. Patent No. 4,374,733 issued to Snyder, et al. (Snyder '733) and U.S. Patent N . 4,255,259 issued to Hwa, et al. (Hwa)[1]

The Ii patent discloses use in cooling water systems of scale and corrosion prevention compositions comprised of a polymeric component in combination with one or more compounds selected from the group consisting of inorganic phosphoric acids and water soluble salts thereof, phosphonic acids and water soluble salts thereof, organic phosphoric acid esters and water soluble salts thereof, and polyvalent metal salts. Although the Ii polymeric component may contain maleic acid and styrene monomers, there is no disclosure of the specific copolymer, SSMA, required in applicant's claims.

The Snyder '733 patent discloses a method for treating cooling water systems prone to scale formation by the addition of a composition comprised of an acrylic acid/lower alkyl/hydroxy acrylate copolymer and another polymeric component, which may be SSMA or a styrene/maleic anhydride (SMA) copolymer. The Snyder '733 patent notes that boiler and cooling water systems share a common problem in regard to scale deposit formation and that use of SMA to prevent scale in boiler water systems is known.

The Hwa patent is directed to a method for treating boiler water systems that are prone to scale formation by addition of a composition comprised of SSMA and an organo-phosphorus acid compound.

The remaining references, cited with respect to certain dependent claims, contain no suggestion to use SSMA, the specific copolymer recited in the appealed claims.

Based upon the prior art and the fact that each of the three components of the composi-

[1] Hwa was cited only with respect to dependent claims 47 and 49.

tion used in the claimed method is conventionally employed in the art for treating cooling water systems, the board held that it would have been prima facie obvious, within the meaning of 35 U.S.C. § 103, to employ these components in combination for their known functions and to optimize the amount of each additive. The board further held that data appearing in appellant's specification, and supplemented by a declaration submitted pursuant to 37 C.F.R. § 1.132, provided insufficient evidence of nonobviousness to rebut the prima facie case.

Issues

1. Whether the board erred in finding that a prima facie case of obviousness was established.

2. Assuming that a prima facie case of obviousness was established, whether the board erred in finding that appellant's objective evidence with regard to unexpected results was insufficient to rebut that prima facie case.

Analysis

Obviousness is a question of law based upon the factual inquiries mandated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). *Bausch & Lomb, Inc. v. Barnes-Hind/ Hydrocurve, Inc.*) 796 F.2d 443, 447, 230 USPQ 416, 419 (Fed. Cir. 1986). For a conclusion of obviousness, the standard of review is correctness or error as a matter of law. In re *Caveney*, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed. Cir. 1985); *In re DeBlauwe*, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).

[1] Appellant contends that the PTO failed to establish a prima facie case of obviousness and, consequently, that the board's affirmance of the examiner's rejections was erroneous. Appellant argues that the PTO's position represented hindsight reconstruction or, at best, established that it would have been "obvious to try" various combinations of known scale and corrosion prevention agents, including the combination recited in the appealed claims.

We agree with appellant that the PTO has failed to establish a prima facie case of obviousness. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). We are convinced that the latter are not present here.

Ii does not suggest use of SSMA as its claimed polymeric component and does not require the presence of an organophosphorus acid compound or of a zinc compound. Ii notes that it is difficult to maintain a predetermined concentration of polyvalent metal ions, such as the zinc (II) ion, in alkaline cooling water, but states that its claimed polymeric component prevents the "polyvalent metals from becoming insoluble compounds and precipitating. . . ." Although Snyder '733 discloses use of SSMA, it is for the purpose of showing that it, or one of three other specifically recited copolymers, may be used in combination with yet another polymeric component, an acrylic acid/lower alkyl/hydroxy acrylate copolymer, to prevent scale formation. With respect to claims 47 and 49, Hwa does disclose the specifically-recited organo-phosphorus acid compound. It provides, however, no suggestion to add a zinc compound to its disclosed combination of SSMA and organ-ophosphorus acid compounds, or to use SSMA in combination with an organo-phosphorus acid compound in the treatment of a cooling water system, where the characteristics may significantly differ from those in Hwa's boiler water system. Hwa also provides no suggestion that SSMA could prevent precipitation of the zinc (II) ion in alkaline cooling water in the manner ascribed to the polymeric component of Ii.

At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, this is not the standard of 35 U.S.C. § 103. *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978); *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966).

Because we reverse on the basis of failure to establish a *prima facie* case of obviousness, we need not reach the issue of the sufficiency of the showing of unexpected results.

REVERSED

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ıching suggestion or incentive
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precipitating. . . ." Although
iscloses use of SSMA, it is for
showing that it, or one of three
lly recited copolymers, may be
ination with yet another poly-
ent, an acrylic acid/lower al-
acrylate copolymer, to prevent
on. With respect to claims 47
does disclose the specifically
o-phosphorus acid compound,
owever, no suggestion to add a
d to its disclosed combination
l organ-ophosphorus acid com-
use SSMA in combination with
osphorus acid compound in the
a cooling water system, where
ristics may significantly differ
n Hwa's boiler water system.
vides no suggestion that SSMA
t precipitation of the zinc (II)
ıe cooling water in the manner
he polymeric component of Ii.

ı view of these disclosures, one
art might find it obvious to try
binations of these known scale
n prevention agents. However,
standard of 35 U.S.C. § 103. *In*
576 F.2d 375, 377, 198 USPQ
1978); *In re Antonie*, 559 F.2d
PQ 6 (CCPA 1977); *In re Tom*
F.2d 928, 150 USPQ 623
6).

ve reverse on the basis of failure
a *prima facie* case of obvious
ed not reach the issue of the
of the showing of unexpected

ED

Newman, Circuit Judge, concurring.

I agree in the court's result, but respectfully do not share the view that the PTO did not present a prima facie case that the claimed invention would have been obvious in terms of 35 U.S.C. § 103. I write separately because the determination of whether a prima facie case of obviousness has been made is a critical decision that controls the evidentiary procedures and burdens before the PTO.

The claims are directed to a three-component system to control scale and corrosion in cooling water systems, the components being (1) zinc ions, (2) a copolymer of sulfonated styrene and maleic anhydride (SSMA), and (3) an organophosphorus acid or salt. A three-part system is described in the Ii reference for the same purpose, but differs from applicant's system in that the copolymer component (2) is different. There is no teaching of SSMA in the Ii reference. However, the Snyder '733 reference teaches SSMA in combination with other polymers to control scale in cooling water systems. The use of SSMA in cooperation with phosphonate is known to reduce scale and sludge in boilers (Hwa). Hwa does not use zinc ions and it is known that zinc ions produce undesirable results in boilers, but the Ii reference states that it was known to use zinc ions alone or in combination with organophophorus acids or salts to inhibit corrosion in cooling water.

Thus each of Geiger's three components has been described, separately or in partial combination, for use in cooling water systems. In my view, it would have been prima facie obvious to replace the polymer component of Ii with the known scale inhibitor SSMA, or to add an organophosphorus compound and zinc ions, both known corrosion inhibitors, to SSMA to achieve both scale and corrosion resistance in cooling water systems. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); *Minnesota Mining & Manufacturing Co. v. Appleton Co.*, 213 USPQ 1024, 1033–34 (E.D. Wis. 1981). The Board so held.

The applicant, in rebuttal of the PTO's prima facie case, argued that his three [component systems exhibits superior properties, and that the superiority was not obvious in view of the cited references. In support of this argument the applicant relied on experimental data in the specification.

The specification contains data on the corrosion/scale control capability of various combinations of components, including data comparing the applicant's three-part system containing SSMA with other three-part systems containing other preferred scale-preventing polymers of the prior art. These data showed significant superiority of applicant's system; this was not disputed. The Board nevertheless held that the prima facie case was not rebutted because the applicant did not include data showing the properties of SSMA alone, stating that "the superior performance of such compositions may be due to the superiority of SSMA vis-a-vis the other scale-Preventing copolymers."

I agree with the Board to the extent that it would have been of scientific interest to include such data. However, as a matter of law I believe that the applicant's showing was reasonable and sufficient. He complied with the requirement that the comparative showing "must be sufficient to permit a conclusion respecting the relative effectiveness of applicant's claimed compounds and the compounds of the closest prior art," *In re Payne*, 606 F.2d 303, 316, 203 USPQ 245, 256 (CCPA 1979), and must "provide an adequate basis to support a legal conclusion of unobviousness." *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984). The applicant demonstrated the exceptional corrosion inhibition achieved with his three-part system in comparison with systems containing the known corrosion inhibitors zinc ion and organophosphorus compounds. He also compared his combination with systems containing other known polymeric scale inhibitors such as those taught by Ii, and demonstrated that those systems did not provide the improvement in corrosion and scale control achieved with the SSMA combination. He also demonstrated that neither polymaleic anhydride nor sulfonated polystyrene had the same effect on corrosion resistance as did the SSMA copolymer.

Applicant compared his system with the most relevant prior art. It is not required that the claimed invention be compared with subject matter that does not exist in the prior art. The applicant is not required to create prior art, nor to prove that his invention would have been obvious if the prior art were different than it actually was.

The Board also upheld the examiner's additional rejection that it would have been obvious to add zinc ion to the two-component SSMA/phosphonate system of Hwa. The Hwa system is for the reduction of scale and sludge at the high temperatures of steam

boilers, and it was uncontroverted that zinc ion is not usable at high temperatures. Applicant provided data showing that the Hwa system is relatively ineffective in a cooling system. The Board did not contradict this position on its scientific merits.

The applicant compared SSMA/phosphonate (Hwa) alone, SSMA/zinc, and phosphonate/zinc, with his three-component system, and achieved results that the Board held showed "superior performance." These results are sufficient in themselves to rebut a prima facie case of obviousness. *See In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Turning to the rejection on the breadth of the claim language, the limitations in the claims appear to be reasonably commensurate with the disclosure. Although I do not agree with the applicant that it is incumbent on the Commissioner to offer "technical evidence", applicant's specific examples are illustrative of the limitations described in the specification, and are not in themselves further limitations. *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977); *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).

Court of Appeals, Federal Circuit

S and T Manufacturing Co. v. County of Hillsborough, Florida

No. 86-1484

Decided March 31, 1987

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Settlement agreements; consent decrees; waivers; releases (§410.43)

Federal district court did not err in finding that enforceable settlement agreement had been reached between patent infringement parties, despite plaintiff's argument that agreement was "agreement to agree" because no adequate drawing of noninfringing structure was prepared, since drawing at issue was initialed and referenced as showing acceptable noninfringing structure.

REMEDIES

2. Monetary remedies — Damages — In general (§510.0501)

Defendant in patent infringement suit is entitled to damages under Fed.R.App.P. 38, in view of plaintiff's frivolous appeal of federal district court's decision that parties' settlement agreement was enforceable.

Appeal from District Court for the Middle District of Florida, Castagna, J.

Action by S and J Manufacturing Co. Inc., Saul R. Spector, and Steco Sales Inc., against the County of Hillsborough, Florida, et al., for patent infringement. From decision denying plaintiff's motion to set aside and granting defendant's motion to enforce settlement agreement, plaintiff appeals. Affirmed.

Leonard Michael Quittner, Reading, Pa., for appellants.

Edward Kondracki, of Kerkham, Stowell, Kondracki & Clarke, Falls Church, Va., and George Rahdert, of Rahdert, Acosta & Dickson, St. Petersburg, Fla. (William L. Feeney, of Kerkham, Stowell, Kondracki & Clarke, Falls Church, Va., Joseph Spicola, of Rahdert, Acosta & Dickson, St. Petersburg, Fla., and R. Elliott Dunn, Tampa, Fla., with them on the brief), for appellees.

Before Nies, Bissell, and Archer, Circuit Judges.

Bissell, Circuit Judge.

S and T Manufacturing Co., Inc., Saul R. Spector, and Steco Sales, Inc. (collectively, S&T) seek to overturn the final order of the United States District Court for the Middle District of Florida, Civil Action 84-1431-Civ-T-15. The order denied S&T's motion to set the case on the district court's trial docket and granted the motion filed by the County of Hillsborough, Florida, Har-Dee Manufacturing Co., Plant City Steel Co., Harsco Corp., and Hunt Truck Sales and Services, Inc. (collectively, Hillsborough) to enforce the settlement agreement. The district court found that the settlement agreement between S&T and Hillsborough was enforceable and that S&T had failed to show a basis for voiding the agreement. We affirm.

BACKGROUND

This case arises out of a patent infringement dispute concerning U.S. Patent No. 3,815,764. The parties with their counsel

fees to any *consumer* who has loss as a result of a violation of the he choice of the word "anyone" of the word "consumer" in), therefore, seems deliberate, and iat the scope of the enjoinder rem- ater than that of the actual damage

ourt in *L.J.S. Co. v. Marks*, 480 41 (S.D.Fla. 1979), while denying sumer damages under the Act, im- t a declaratory judgment and an n would have been available. Fur- , in *United Feature Syndicate, Inc. se Mold Co.*, 569 F.Supp. 1475 , 1983) (J. Paine), the Court con- ie Act to protect owners of copy- om infringement.

though the statute is generally di- traditional consumer transactions urpose is to protect the unsophisti- m being conned into unsound invest- *See Black v. Department of Legal* 468 So.2d 451 (1985); the extension atute's scope to others damaged by ade practices is not unique. Many ions have interpreted similar con- protection statutes to encompass rk violations that could cause confu- l misunderstanding to the average er. Therefore, it is:

ERED AND ADJUDGED that De- s' motion is hereby DENIED.

Industries v. I.C. Indus., 595 F.Supp. D.Fla. 1983) the court construed Section (3) to exclude trademark cases from the t Section excludes "a claim for damage to other than the property that is the subject consumer transaction." Nothing in that however, excludes Plaintiff from seeking *atory judgment* and an *injunction* to pre- tinued infringement of its trademark. 89 ALR 3d 449, 468 for cases where eld that the use of tradenames constituted on of a deceptive trade practice statute or er protection act.

Court of Appeals, Federal Circuit

Akzo N.V. v. U.S. International Trade Commission

No. 86-877

Decided December 22, 1986

PATENTS

1. Patentability/Validity — Anticipation — Prior art (§115.0703)

U.S. International Trade Commission did not use impermissible "ipsissimus verbis" test in finding that claimed process for making aramid fibers was not anticipated, but rather properly found that prior art did not disclose such process to one of ordinary skill in art and that prior art reference that called for use of sulfuric acid did not call for use of 98 percent concentration critical to success of claimed process, since "concentrated sulfuric acid" is not inherently 98 percent sulfuric acid to one skilled in art.

2. U.S. International Trade Commission — In general (§115.01)

International Trade Commission's administrative protective order which permitted access, to confidential business information produced during discovery phase of investigation, by both parties' outside counsel, but not by management personnel or in-house counsel of either company was proper, since order did unilaterally immunize purportedly confidential documents from scrutiny of party challenging order, since order provided mechanism by which either party was free to object to designation of information as confidential, and since party challenging order failed to prove need for access to such information, nor harm to it from nondisclosure.

3. U.S. International Trade Commission — Burden of proof (§115.05)

International Trade Commission did not err in determining that unlawful importation of infringing aramid fibers violated Tariff Act's Section 337, 19 USC 1337, based upon its finding, supported by substantial evidence, that such importation will have tendency to injure domestic industry, despite evidence that domestic industry's profits from sale of fibers will increase notwithstanding such entry into market, since issue under Section 337 is not whether domestic industry profits will increase beyond current levels but whether importer's presence in market will substantially injure domestic industry's business during remaining life of patent.

4. U.S. International Trade C mmission — Jurisdiction (§115.03)

International Trade Commission proceeding under Tariff Act's Section 337, 19 USC 1337, is not "inherently judicial" proceeding that must be adjudicated only by Constitution's Article III courts, even though private rights may be affected by Section 337 proceedings, since main thrust of Section 337 is to protect public interest from unfair trade practices in international commerce, and since Section 337 represents valid delegation of broad congressional power to achieve such purpose.

Appeal from U.S. International Trade Commission.

U.S. International Trade Commission investigation on behalf of E.I. du Pont de Nemours and Co., for exclusion of certain aramid fibers covered by U.S. patent, in which Akzo N.V., Enka B.V., Aramide Maatschappij v.o.f., and Akzona Incorporated, were designated as respondents. From exclusion order prohibiting importation, respondents appeal. Affirmed.

Denis McInerney, and Cahill Gordon & Reindel, both of New York, N.Y., C. Frederick Leydig, and Leydig, Voit & Mayer, Ltd., both of Chicago, Ill., and Tom M. Schaumberg, Cecilia H. Gonzalez, and Plaia & Schaumberg, Chartered, all of Washington, D.C. (David R. Hyde, Laurence T. Sorkin, George Wailand, P. Kevin Castel, Charles S. Oslakovic, John Kilyk, Jr., Norval B. Galloway, and Robert H. Falk, and Hubbard, Thurman, Turner & Tucker, both of Dallas, Texas, on the brief), for appellants.

Catherine Field, Office of the General Counsel, U.S. International Trade Commission (Michael P. Mabile, assistant general counsel, on the brief), for appellee.

Daniel M. Gribbon, and Covington & Burling, both of Washington, D.C., Joseph M. Fitzpatrick, and Fitzpatrick, Cella, Harper & Scinto, both of New York, N.Y. (Harris Weinstein, James R. Atwood, Eugene D. Gulland, Dwight C. Smith, III, and Stephen H. Marcus, and John A. O'Brien, Henry J. Renk, Charles P. Baker, Laura A. Bauer, and Bruce C. Haas, on the brief), for intervenor-appellee E.I. du Pont de Nemours.

Before Markey, Chief Judge, and Davis and Nies, Circuit Judges.

Davis, Circuit Judge.

This is an appeal by Akzo, N.V., Enka B.V., Aramide Maatschappij v.o.f. and Akzona Inc. (appellants or Akzo) from an exclusion order by the United States International Trade Commission (Commission or trial tribunal) pursuant to §§337 and 337a of the Tariff Act of 1930, 19 U.S.C. §§1337, 1337a (1982), prohibiting the importation into the United States of aramid fibers manufactured by Akzo in the Netherlands. We affirm.

I. *Background; Issues; Scope of Review*

A. Background. On April 18, 1984, E.I. du Pont de Nemours and Company (appellee or Du Pont) filed a complaint with the Commission under §337 of the Tariff Act of 1930 (19 U.S.C. §1337).[1] The complaint alleged that Akzo had engaged in unfair methods of competition and unfair acts including the importation, sale and marketing in the United States of certain aramid fibers.[2] produced in the Netherlands by a process purportedly covered by the claims of Du Pont's U.S. Letters Patent No. 3,767,756 (the Blades or '756 patent). In addition, the complaint charged Akzo with attempting both to exploit applications of aramid fibers and to penetrate markets for aramid fibers created by Du Pont. Finally, the complaint alleged that the effect or tendency of the unfair methods of competition and unfair acts was to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

After evaluating Du Pont's complaint, the Commission instituted an investigation pursuant to §337(b), 19 U.S.C. §1337(b), and an administrative law judge (ALJ) was assigned to preside over the investigation.

The major substantive question before the ALJ (and now before us) is the validity and enforceability of Du Pont's Blades patent. Those issues, and the related facts and circumstances, are set forth and discussed in Part II, *infra*. The major procedural issue is whether Akzo was denied due process because Du Pont's confidential documents were not disclosed to appellants' management. This problem (together with an alleged violation of treaty rights) is considered in Part III, *infra*. The other issues presented to us are dealt with in Part IV, *infra*.

Following 14 days of hearing the ALJ issued an initial determination holding that there was a violation of §337(a) of the Tariff Act of 1930 in the unlawful importation or sale of certain aramid fibers produced overseas by means of a process that if practiced in the United States would infringe the Blades '756 patent, and that importation has the tendency to injure substantially an efficiently and economically operated industry in the United States.

Akzo filed a petition for review of the ALJ's initial determination on June 3, 1985. On July 15, 1985, the Commission decided to review only those portions of the initial determination pertaining to anticipation and obviousness of the Blades '756 patent under 335 U.S.C. §§102 and 103. Ultimately, the Commission affirmed the ALJ's findings and conclusions on anticipation and obviousness and determined that appellants had failed to prove the Blades '756 patent invalid. Having decided not to review the remainder of the initial determination, the Commission concluded that there was a violation of §337. Accordingly, on November 25, 1985, the Commission, after further consideration, entered an exclusion order limited to certain forms of aramid fibers produced by Akzo. The Commission's order became final on January 25, 1986 when the President declined to overrule it pursuant to §337(g).

B. *Issues.* On this appeal, Akzo raises a number of issues for us to resolve:

(1) whether the Commission's finding that claim 13 of the '756 patent was "not invalid" and "not unenforceable" is supported by substantial evidence;[3]

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[1] 19 U.S.C. §1337 (1976) provides in pertinent part:

Unfair practices in import trade

(a) Unfair methods of competition declared unlawful

Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are declared unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section.

[2] As indicated in Part II, *infra*, aramid fibers are the strongest commercial synthetic fibers known to man — about five times stronger than steel on an equal weight basis..

[3] Akzo presents no contention that, if claim 13 of the '756 patent is valid and enforceable, Akzo would not infringe if it used its same process in this country.

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[3] Akzo presents no contention that, if claim 13 of the '756 patent is valid and enforceable, Akzo would not infringe if it used its same process in this country.

(2) whether Akzo's due process and treaty rights were violated in the Commission proceeding;

(3) whether the Commission, as a non-Article III tribunal, is constitutionally prohibited from adjudicating the validity and enforceability of patents;

(4) whether the Commission's finding that Akzo's sales of aramid fibers in the United States would have a tendency to "destroy or substantially injure" an industry economically and efficiently operated is supported by substantial evidence;

(5) whether the Commission's conclusion that Du Pont's value-in-use pricing did not violate the antitrust laws is correct and supported by substantial evidence; and

(6) whether it is a defense to Du Pont's complaint that Du Pont employed a solvent included in a polymerization process patented by Akzo.

C. *Scope of review.* This court defined our scope of review in cases appealed from the Commission in *Beloit Corp. v. Valmet OY*, (Order), 742 F.2d 1421, 223 USPQ 193 (1984), *cert. denied*, 105 S. Ct. 2706, 86 L. Ed. 2d 721 (1985). There we held that the court "does not sit to review what the Commission has not decided." 742 F.2d at 1423, 223 USPQ at 194. *Beloit* is distinguishable from this case because there the Commission specifically adopted only a portion of the presiding official's initial decision. *See, e.g., American Hospital Supply Corp. v. Travenol Laboratories, Inc.*, 745 F.2d 1, 5 n.13, 223 USPQ 577, 580 n.13 (Fed. Cir. 1984). In contrast, in the current case, the Commission merely determined not to review the remainder of the initial decision, choosing to conduct its own §§102 and 103 analysis. The Commission neither rejected any part of the initial determination nor did it say that it was taking no position on any part of it. Although the Commission limited its own review to patent validity under §§102 and 103, the fact that it affirmed the conclusion of the ALJ that there as a §337 violation makes reviewable those conclusions of the ALJ necessary for the Commission to have determined (as it did) that there was a §337 violation. *Accord Warner Brothers, Inc. v. U.S. International Trade Commission*, 787 F.2d 562, 229 USPQ 126 (Fed. Cir. 1986). This includes not only the §§102 and 103 issues of anticipation and obviousness, but also whether there was inequitable conduct before the Patent Office and the other issues decided by the Commission and the ALJ.[4]

[4] 19 C.F.R. §210.53(h)(1986) provides that "[a]n initial determination . . . shall become the determination of the Commission . . . unless the Commission . . . shall have ordered review of the initial determination or certain issues therein . . . ." In accepting the necessary conclusions of the ALJ we do not hold that the Commission must have concurred with each and every individual factual finding of the ALJ to support its conclusion.

II. Validity and Enforceability of the Blades Patent

A. *The Invention.*[5] The Blades '756 patent, "Dry-Jet Wet Spinning Process," was issued on October 23, 1973 to Dr. Herbert Blades and immediately assigned to Du Pont. The patent describes a method that produces a high strength synthetic polyamide[6] fiber which Du Pont has marketed under the trade name Kevlar. This fiber has an extraordinary as-spun strength, five times stronger pound for pound than steel, as well as a modulus (stretch resistance) equal to glass, eight times as high as industrial grade polyester, and twenty-five times as high as industrial nylon. Kevlar is also much more heat resistant than industrial-grade nylon or polyester. These extraordinary physical properties, as well as Kevlar's light weight and rustproof character, have enabled Du Pont to market it for use in a variety of applications including, but not limited to, roping, spacecraft and airplane parts, bullet resistant clothing and armor, tires, and boat hulls. Depending upon its use, Kevlar has been used as a substitute for steel, aluminum, asbestos, nylon, rayon, polyester, cotton, or cotton fiber. Kevlar is available as either a continuous rope or filament, or alternatively as a staple or pulp. Staple consists of short filaments which can be spun into yarn. Pulp is ground fiber most often used as an asbestos substitute.

The procedure by which the synthetic fiber is manufactured involves dry spinning polyamides from coagulation solutions called dopes. In dry spinning, a specialized filter called a spinneret is placed a short distance from a bath of spinning dope that is extruded through a layer of gas and into an aqueous

[5] Our recitation of the facts follows the ALJ's and the Commission's findings which are supported by at least substantial evidence. *See Surface Technology, Inc. v. U.S. International Trade Commission*, 801 F.2d 1336, 1340, 231 USPQ 192, 195 (Fed. Cir. 1986).

[6] Polyamides are polymers containing amide linkages. Aromatic polymers are polyamides where the radicals linking the amide linkages constitute aromatic radicals. The polymer described in claim 13 of the Blades '756 patent is a wholly aromatic para-positioned polyamide.

coagulation bath.[7] The dope used in the Blades '756 patent consists of para-positioned aromatic polyamides dissolved in highly concentrated sulfuric acid and heated to around 100°C. The polyamide used is a high molecular weight poly(p-phenylene terephthalamide) (PPD-T).

The high molecular weight of the polyamide results in a high inherent viscosity[8] of approximately 4.4% when 20% PPD-T by weight is dissolved in approximately 100% sulfuric acid.

In 1969 Dr. Blades, one of Du Pont's research scientists, began to develop and conduct experiments aimed at producing a high-strength synthetic fiber. Blades exclusively employed a wet-spinning method in his early work, using PPD-T as well as other polymers. This early work had minimal success. Although the dry-spinning method was known by Du Pont scientists, a 1966 report indicated that the low solubility of PPD-T precluded use of the dry-spinning technique. In 1969, Du Pont's Dr. Peter Boettcher suggested to Blades that dry spinning might improve the end-results by influencing coagulation. Dr. Boettcher had learned about dry spinning from a Monsanto Morgan patent (Morgan '645 patent).

Blades' early experimentation with the dry-spinning process did not yield fiber with an increased tenacity despite the fact that dry spinning was known to improve fiber tenacity using other dopes. Blades' initial conclusion was that dry spinning would be unsuccessful with PPD-T. Nevertheless, he continued experimenting with the dry-spinning process, and, at his supervisor's suggestion, began using sulfuric acid as a solvent. Blades also redesigned and built a mixing device because of some difficulties he encountered mixing PPD-T with the sulfuric acid. Sulfuric acid was not an evident candidate as a solvent because it was known to react with the polymer and become degraded at high temperatures. Blades discovered, however, that he could produce an improved fiber using 10.2% polyamide in about 100% sulfuric acid. Under this system he found that there was no difference in tensile strength of the fiber using a wet-spun or dry-spun method. PPD-T was a somewhat unusual choice of polymer for this work because of its characteristic rigidity caused by the placement of para-oriented aromatic rings in the chain. The para-positioning of the aromatic rings makes the polyamide much less soluble than analogous meta-positioned rings. But the fact is that, while meta-positioned polymers generally form only isotropic solutions, para-positioned polymers of Blades' invention form anisotropic solutions[9] at high concentrations.

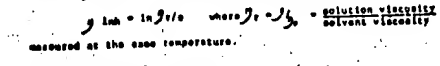
In subsequent trials, Blades increased the concentration of PPD-T and obtained a significantly improved fiber, especially using the dry-spinning method. When the system was operated at room temperature, however, he found that undissolved polyamide clogged up the holes of the spinneret. He therefore heated the dope at these higher concentrations to dissolve all the polyamide and keep the system above the melting point. To his surprise, Blades discovered that there was little or no degradation of the polyamide at high temperatures. He explained this unexpected absence of degradation by theorizing that, when the system contains high concentrations of PPD-T, the sulfuric acid binds to the polymer and chemically deactivates it.

After numerous trials, Blades found that an optional fiber could be produced using PPD-T of 4.4 inherent viscosity at a 20% concentration in approximately 100% sulfuric acid. The dope was then heated to 95°C and dry spinning was then carried out at about 100°C. The resultant fiber had a tenacity of approximately two times that of previous experimental fibers.

In April 1971, Blades filed an application with the PTO claiming the method of making these aramid fibers. the initial application and two subsequent applications were rejected in large part on the basis of anticipation by the Morgan '645 and the Kwolek '542 patents which Du Pont had brought to the attention of the examiner. Initially the

[7] Dry spinning can be contrasted with wet spinning where the spinneret is placed directly into the spinning dope. Wet spinning is the process used to make a number of synthetic fibers including rayon and nylon.

[8] Inherent viscosity (inh) is a measure of viscosity used in polymer chemistry.



measured at the same temperature.

[9] An anisotropic solution exhibits optical birefringence (i.e., the liquid crystalline solution refracts light in two directions). This characteristic imparts a high degree of orientation to the spun fibers yielding a stiffer and stronger end product without requiring post-coagulation drawing as is required is other man-made fibers such as nylon and rayon.

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subsequent trials, Blades increased the ntration of PPD-T and obtained a sig-ntly improved fiber, especially using ry-spinning method. When the system perated at room temperature, however, und that undissolved polyamide clogged ıe holes of the spinneret. He therefore d the dope at these higher concentra- to dissolve all the polyamide and keep ystem above the melting point. To his ise, Blades discovered that there was or no degradation of the polyamide at temperatures. He explained this unex-d absence of degradation by theorizing when the system contains high concen-ons of PPD-T, the sulfuric acid binds to olymer and chemically deactivates it.

fter numerous trials, Blades found that ptional fiber could be produced using -T of 4.4 inherent viscosity at a 20% entration in approximately 100% sulfu- cid. The dope was then heated to 95°C dry spinning was then carried out at ıt 100°C. The resultant fiber had a te-ty of approximately two times that of ious experimental fibers.

ı April 1971, Blades filed an application ı the PTO claiming the method of mak-these aramid fibers. the initial applica- and two subsequent applications were cted in large part on the basis of anticipa- by the Morgan '645 and the Kwolek 2 patents which Du Pont had brought to attention of the examiner. Initially the examiner also rejected the application under 35 U.S.C. §103. Blades, however, was able to overcome the examiner's objections, and on May 2, 1973, the PTO gave notice of allowance of the Blades '756 patent. Blades assigned the patent rights to Du Pont.

B. *Validity*. Claim 13, the narrowest claim, is the only claim involved on this appeal.[10] Akzo says that that claim is invalid under 35 U.S.C. §§ 102 and 103. More specifically, Akzo argues that the Commission misconstrued the legal standard of anticipation and therefore erroneously held that the Blades '756 patent was not anticipated. In addition, appellants argue that the Commission failed properly to evaluate the prior art in determining obviousness *vel non*. Of course, it goes without elaboration that the Blades '756 patent enjoys a presumption of validity under 35 U.S.C. §282.

[1] As we have said, Akzo challenges the Commission's use of §102, claiming that that tribunal misinterpreted the legal standard of anticipation. Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964). Akzo asserts, however, that the Commission wrongly used an *"ipsissimis verbis* test" in reaching its conclusion that the Blades '756 patent was not anticipated by the Morgan '645 disclosure.[11] We do not read the Commission's opinion as requiring such an *"ipsissimis verbis* test." Rather, we understand that opinion as simply finding that the prior art reference did not disclose, to one of ordinary skill in the art,[12] the process for making the aramid fibers described in claim 13. The Commission noted that while the Morgan '645 patent called for the use of sulfuric acid, it did not call for the use of at least 98% concentrated sulfuric acid which was critical for the success of the Blades process. The Commission also concurred with the ALJ and found that concentrated sulfuric acid is not inherently 98% sulfuric acid to one skilled in the art.

Because we determine that the Commission did not use an incorrect legal standard under §102, we are bound to accept its and the ALJ's factual findings if supported by substantial evidence. 5 U.S.C. §706 (1982). As appellants themselves point out, anticipation under §102 is a factual determination. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). We must conclude that there is substantial evidence in the record supporting the Commission's conclusion that claim 13 of the Blades '756 patent was not anticipated by the prior art. As the Supreme Court noted in *Universal Camera v. NLRB*, 350 U.S. 474, 488 (1951), the substantial evidence standard does not allow a court to conduct a *de novo* investigation of the evidence on the record before it and reach an independent conclusion; rather, the court's review is limited to deciding whether there is sufficient evidence in the record considered as a whole to support the agency's findings. The mere fact that a reasonable person might reach some other conclusion is insufficient for this court to overturn the agency's conclusion. *See SSIH Equipment S.A. v. U.S. International Trade Commission*, 718 F.2d 365, 381, 218 USPQ 678, 691 (Fed. Cir. 1983) (additional views of Judge Nies).

The ALJ concluded, after extensive analysis, that the claimed invention of the Blades '756 patent was not anticipated by prior art, including the Morgan '645 patent. He noted that, while the Morgan '645 patent teaches the use of an airgap, the use of airgap in and of itself does not guarantee an improved fiber. This was obvious from Blades' early work. The ALJ also found that sulfuric acid in any concentration was not disclosed as a solvent in the Morgan '645 patent; or did that patent disclose PPD-T in its optically anisotropic state. Moreover, the ALJ found that the Morgan '645 patent was not an enabling disclosure with regard to the claimed spinning dope. Neither the 18% concentration of PPD-T nor the heating of the dope to achieve this concentration was disclosed in the Morgan '645 patent. The ALJ also rejected appellants' arguments that the

An anisotropic solution exhibits optical biregence (i.e., the liquid crystalline solution re-ts light in two directions). This characteristic arts a high degree of orientation to the spun rs yielding a stiffer and stronger end product ıout requiring post-coagulation drawing as is uired is other man-made fibers such as nylon rayon.

[10] Claim 13 reads as follows:
A method comprising extruding a spinning dope from an orifice through a layer of gas and into an aqueous bath at a temperature of under 50°C said dope comprising a polyamide and a solvent of sulfuric acid of at least 98% concentration at a concentration of at least 40 grams of said polyamide per 100 ml. of solvent, said polyamide having an inherent viscosity of at least 3.0 and being poly(p-phenylene terephthalamide).

[11] An *"ipsissimis verbis"* test requires the same terminology in the prior art in order to find anticipation.

[12] The Commission made specific findings on the skill of the art. It concluded that the skill in the art was high — that of a doctorate or post-doctorate in chemistry.

Blades process was anticipated by the Hill and Smith patents which were referenced in the Morgan '645 patent. This would have required Blades randomly to pick and choose among a number of different polyamides, a plurality of solvents, and a range of inherent viscosities. The ALJ rejected such "random picking and choosing" of prior art, relying on *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972), and concluded in effect that the anticipatory reference must disclose in the prior art a thing substantially identical with the claimed invention. In a somewhat more limited consideration — restricted to the concentration of sulfuric acid in the Blades patent — the Commission itself reached the same result.

Accordingly, we hold that there is substantial evidence in the record as a whole to sustain the Commission's (including the ALJ's) findings that the Blades process was not anticipated by any prior art.[13]

Appellants say, as an alternative to their §102 argument, that the trial tribunal erred when it failed to find that the Blades '756 patent would have been obvious under 35 U.S.C. §103 in view of the Morgan '645 and Kwolek '542 patents. It is now established that obviousness is a question of law based on factual inquiries which include:

(1) the scope and content of the prior art;
(2) the difference between prior art and the claims at stake;
(3) the level of ordinary skill in the art; and
(4) objective evidence of nonobviousness (secondary factors).

Such objective indications as commercial success and long-felt but unresolved needs, failure of others, copying, and unexpected results are relevant facts relating to the issue of validity. *See, e.g., In re DeBlauwe*, 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984) (obviousness a question of law to be determined on the facts). Since obviousness is a question of law, we are not bound by the Commission's ultimate determination on the matter of §103 obviousness. *See Corning Glass Works v. U.S. International Trade Commission*, 799 F.2d 1559, 1565 & n.5, 230 USPQ 822, 826 & n.5 (Fed. Cir. 1986).

In the proceedings before the Commission, Du Pont premised its defense of nonobviousness on the basis that the prior art — mainly that the Morgan '645 patent and the Kwolek '542 patent — actually led away rather than toward the Blades process. The Commission found Du Pont's expert witness' testimony to be compelling. That witness, Dr. Uhlmann, explained why the Morgan '645 patent, when considered with other prior art references, including the Kwolek '542, Bair '941, and Cipriani '793 patents, would not have rendered the invention of Blades '756 patent obvious. The Kwolek '542 patent calls for conventional wet or dry spinning and calls for concentrations of PPD-T far lower than required by the Blades process. The Bair '941 patent does not disclose heating sulfuric acid with PPD-T to achieve an anisotropic solution. While the Morgan '745 patent discoses air-gap spinning, its emphasis is on meta-oriented polymers. Based on these differences, Dr. Uhlmann concluded that one skilled in the art would *not* combine them or be led to the Blades invention.

As the ALJ recognized, prior art references before the tribunal must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Moreover, appellants cannot pick and choose among individual parts of assorted prior art references "as a mosaic to recreate a facsimile of the claimed invention." 721 F.2d at 1552, 220 USPQ at 312. In this case, the ALJ found that Akzo's expert witnesses could not show how the prior art patents could be brought together to render the Blades '756 invention obvious without reconstructing the teachings of those patents assisted by hindsight.

The secondary considerations also compelled the Commission to make a finding of nonobviousness. The commercial success of Du Pont's Kevlar patent has been enormous and its range of uses substantial. Du Pont is still developing commercial applications for Kevlar, having spent significant amounts of money in developing both new uses and new markets for the product. Commercial success is, of course, a strong factor favoring non-obviousness. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575–76, 222 USPQ 774, 777, (Fed. Cir. 1984), *cert. denied*, 471 U.S. 1065 (1985). Moreover, as the ALJ noted, Blades solved a problem that Du Pont research scientists had

[13] Appellants cite this court's opinion in *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778–79 (Fed. Cir. 1985), as supporting their contention that the Blades '756 patent was anticipated by the prior art. *Titanium Metals* is easily distinguishable from this case. There, a single reference disclosed a range of alloys including that claimed by appellant. In this case, the Commission found that neither the Morgan '645 patent nor any other prior art reference disclosed the Blades '756 process.

Glass Works v. U.S. International Trade Commission, 799 F.2d 1559, 1565 & n.5, 230 USPQ 822, 826 & n.5 (Fed. Cir. 1986).

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We agree, therefore, with the Commission's determination that the Blades '756 patent is not invalid for anticipation or obviousness.

C. *Alleged inequitable conduct before the Patent and Trademark Office (PTO).* Appellants urge that Du Pont misled the patent examiner in two respects: first, that Du Pont submitted an affidavit to overcome the examiner's obviousness objections that failed to compare the Blades process with the closest prior art; and, second, that Du Pont persistently argued that the Morgan '645 patent and the Kwolek '542 patent did not anticipate the Blades patent.

In *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 223 USPQ 1089 (Fed. Cir. 1984), *cert. denied*, 106 S. Ct. 73 (1985), this court articulated a two-prong test for establishing inequitable conduct before the PTO. To render a patent unenforceable, the proponent of the inequitable conduct must first establish by clear and convincing evidence that there was a material misrepresentation or omission of information, and then establish a threshold level of intent on the part of the applicant. *See also Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577-78, 224 USPQ 409, 414-15 (Fed. Cir. 1984).

Our major standard for materiality is whether a reasonable examiner would consider the omission or misrepresentation important in deciding whether to issue the patent.[14] Materiality and intent must also be considered together: the more material the omission or misrepresentation, the less intent that must be shown to reach a conclusion of inequitable conduct. *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1363, 220 USPQ 763, 773 (Fed. Cir.), *cert. denied*, 469 U.S. 821, 224 USPQ 520 (1984).

We uphold the Commission's findings and conclusion that Du Pont's affidavit or arguments before the examiner did not constitute material misrepresentation. As Akzo concedes, the examiner had both the Morgan '645 patent and the Kwolek '542 patents before him throughout the examination process. It was on the basis of these two patents that Du Pont's first three applications were rejected. The mere fact that Du Pont attempted to distinguish the Blades process from the prior art does not constitutes a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the Blades process based on the are in front of him. Nor does Du Pont's affidavit, advocating a particular interpretation of the Morgan '645 and Kwolek '542 patents (albeit favorable to Du Pont's position), show any intent to mislead the PTO. Du Pont's intent was not to mislead, but rather to distinguish prior art from the Blades process and demonstrate to the examiner that the Blades process and demonstrate to the examiner that the Blades process would not have been obvious in light of Morgan '645 and Kwolek '542. The sum of it is that, because we cannot see either a proved material misrepresentation or a proved intent to mislead, we must conclude that Akzo has not met its burden of proving inequitable conduct before the PTO

[14] This standard is identical to the PTO standard of materiality. 37 C.F.R. §1.56(a).

III. *Due Process and Treaty Rights*

A. *Due Process.* This aspect of the appeal concerns the Commission's procedures with respect to the private parties' confidential information. On May 21, 1984, the ALJ issued an administrative protective order pertaining to confidential business information, as defined in the Commission's Rules, 19 C.F.R. §210.30(d)(7) (1976), that would be produced during the discovery phase of the investigation.

In general, this order permitted access to all such confidential information by Akzo's and Du Pont's outside counsel but not by management personnel or in-house counsel of either private company. At a preliminary conference held June 22, 1984, Akzo made the first of three unsuccessful attempts to modify the protective order. Arguing that there was a substantial overlap between the Commission's investigation and an action brought by Akzo against Du Pont them (and still) pending in the United States District Court for the District of Delaware, Akzo moved to align the protective orders by modifying the ALJ's protective order so that its terms coincided with those of a protective order earlier issued by the District Court in the Delaware action. The ALJ denied Akzo's motion on July 6, 1984.

By letter dated June 27, 1984, Akzo requested that the protective order be amended

to include three designated members of Akzo's in-house counsel. On July 6, 1984, the ALJ concluded that Akzo failed to demonstrate the requisite need to warrant granting Akzo's in-house counsel access to Du Pont's confidential business information. Akzo renewed its motion to modify the protective order n February 8, 1985, this time urging that both Akzo's in-house counsel and the general manager of Akzo's Industrial Fiber Group should be granted limited access to Du Pont's confidential business information. Because Akzo failed (in the ALJ's view) to demonstrate a need for either its in-house counsel or its general manager to have access to the requested confidential material, the ALJ denied Akzo's motion on February 21, 1985.

Akzo now contends that the protective order, issued by the ALJ on May 21, 1984, effectively deprived it of its rights to confrontation, to rebuttal, and to effective assistance of counsel. According to Akzo, under the terms of the protective order, the parties' designation of materials as confidential had the effect of "unilaterally immunizing them from scrutiny by the opposing party." Moreover, Akzo maintains that the system established by the protective order completely denied Akzo "access to all of the critical evidence on which the decision against it was based."

[2] Our examination of the challenged protective order, as it was enforced, shows Akzo's charges to be groundless. The protective order provides, *inter alia,* that confidential business information "shall be disclosed at any hearing only *in camera* before the commission or the administrative law judge." Although the protective order enabled either party to designate business information as confidential, such a designation did not "unilaterally immunize" purportedly confidential documents from scrutiny by the opposing party. In the first place, all the protected information was freely available to outside counsel who could fully consider it, although they were not free to show or repeat it to Akzo's management or in-house counsel. Second, paragraph 10 of the protective order provided a mechanism by which either party was free to object to its adversary's designations at any stage of the proceeding. According to paragraph 10, if either party disagreed with respect to the designation of business material as confidential, that party "shall confer [with the supplier] as to the status of the subject information proffered within the context of this order." In the event that the parties failed within 10 days to reach agreement as to the proper status of the information, the protective order provided that either party could submit the issue to the ALJ or the Commission for resolution. The mechanism of paragraph 10 could also be used to permit disclosure to particular persons of otherwise classified material. Although, as mentioned earlier, Akzo attempted to modify the protective order on three separate occasions, Akzo never invoked the dispute resolution procedures of paragraph 10 to challenge Du Pont's characterization of business information as confidential or as not disclosable to particular individuals. Third, the protective order expressly permitted other exceptions to be made by the ALJ or the Commission.

In denying Akzo's various motions to amend the protective order, the ALJ relied on the Commission's decision in *Certain Rotary Wheel Printers,* Inv. No. 337-TA-145, 5 ITRD 1933 (Nov. 4, 1983). According to *Rotary Wheel Printers:*

> [p]rotection of confidential information is crucial to the Commission's ability to carry out its statutory responsibilities. In addition, review after discovery and the evidentiary hearing are completed would provide an inadequate remedy. The inappropriate release of confidential information can never be fully remedied.
>
> The Commission has traditionally been reluctant to release confidential information where not absolutely necessary.

5 ITRD at 1935.

Thus, implicit in Akzo's due process attack on the protective order is the position that, in the interests of fundamental fairness, it was "absolutely necessary" for Akzo's in-house counsel and general manager to have access to Du Pont's confidential business information. However, "[i]n section 337 investigations, it is the exception rather than the rule to release confidential information to in-house counsel." *Id.*

The primary justification for the Commission's reluctance to grant adversary management and in-house counsel access to confidential business information is that, in order to discharge its statutory responsibilties within the strict statutory time limits, the Commission is heavily dependent on the voluntary submission of information. Disclosure of sensitive materials to an adversary would undoubtedly have a chilling effect on the parties' willingness to provide the confidential information essential to the Commission's fact-finding processes. the Commission has resolved the difficult and controversial question of the role of in-house counsel by taking a conservative position on the side of optimum shielding of business

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information. Obviously, where confidential material is disclosed to an employee of a competitor, the risk of the competitor's obtaining an unfair business advantage may be substantially increased. This general Commission position is neither unreasonable nor arbitrary. It represents an approrpriate balancing between the needs demanded by the Commission's process and the parties' need for participation by its in-house personnel.

This is especially true because there is no *per se* rule against disclosure to either a competitor's in-house counsel or management representative. *Rotary Wheel Printers* established, and the ALJ employed, a three-part balancing test to determine whether, to whom, and under what conditions to release confidential information. Factors to be considered include the party's need for the confidential information sought in order to adequately prepare its case, the harm that disclosure would cause the party submitting the information, and the forum's interest in maintaining the confidentially of the information sought. 5 ITRD at 1937.

After reviewing the record, the ALJ concluded that Akzo failed to demonstrate clearly a need for granting access to confidential business information to either Akzo's in-house counsel or key management officials. The ALJ also found that disclosure would cause substantial harm to Du Pont's competitive position. These particular rulings cannot be faulted. The court understands that all information relating to patent validity and enforceability *(see* Part II, *supra)* was promptly made fully available to all. As for the information bearing on the important question of whether Akzo's importation of aramid fibers would tend to destroy or substantially injure Du Pont's business *(see* Part IV, *infra),* it is obvious that that confidential information — relating to Du Pont's business, activities, plans and expectations — should not be made available (unless, perhaps, where absolutely necessary for a fair hearing) to a direct competitor like Akzo. That such full access was not absolutely necessary to appellants' making of their own case is shown by the crucial fact that Akzo was at all times perfectly free to offer its own market projections as well as to reveal its own activities, forecasts, and interpretations. Both sides could present to the Commission their own information on those matters without knowing those of the other side's.

Akzo argues, however, that the denial of its motions to modify the protective order effectively denied its due process right to participate in its own defense. The contention is that Akzo was subjected to serious adverse governmental action on the basis of evidence which Akzo was never permitted to know and "personally" refute. In support of this position, Akzo invokes §555(b) of the Administrative Procedure Act which was made applicable to §337 proceedings by the 1974 Amendments to the Tariff Act of 1930. Under §555(b), "[a] party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding." 5 U.S.C. §555(b). However, Akzo was represented by competent and experienced outside counsel throughout the proceedings; these counsel were aware of all confidential information. Further, Akzo fails to recognize that "the affirmative grant of the right to appear apparently bestowed by Section 555(b) is not blindly absolute, without regard to the status or nature of the proceedings and concern for the orderly conduct of public business." *DeVyver v. Warden, U.S. Penitentiary,* 388 F.Supp. 1213, 1222 (M.D. Pa. 1974) citing *Easton Utilities Commission v. Atomic Energy Commission,* 424 F.2d 847, 852 (D.C. Cir. 1970). Whatever else §555(b) guarantees to parties to an administrative proceeding under §337, it does not mandate disclosure of significant confidential information to in-house counsel and corporate executives of a business competitor — where that information is fully available to outside counsel. Akzo's contention withers in the face of unrefuted evidence that more than 90 people representing Akzo, including numerous expert witnesses and members of the battery of four law firms comprising Akzo's defense team, had unrestricted access to Du Pont's confidential information.

Akzo has also failed to demonstrate that it suffered actual harm under the confidentiality procedures instituted by the ALJ. Although Akzo's insiders were denied access to Du Pont's economic and market forecasts with respect to the production and sale of aramid fibers, Akzo was not prevented (as we have pointed out) from offering its own projections into evidence under the cover of confidentiality. It is difficult to see how Akzo was prejudiced.

Finally, we have neither found nor been directed to any judicial decision in this country mandating, in the circumstances present here, that business confidential information *must* be made to inside management. On the contrary, we are aware, from the practice of our own court, that records in appeals to us are frequently classified in large part, and are presumably not available to the management of the opposing party. Moreover, there are a substantial number of decisions uphold-

ing confidentiality comparable to that accepted by the Commission. Akzo tells us that most of these involved only pretrial discovery (and not evidence at a hearing or trial) and that the others are also distinguishable. We do not stop to examine these arguments because, at the least, these decisions (a) show that there is no holding to the contrary of the one we now make and (b) strongly suggest the validity of carefully tailored protective orders allowing exceptions to be made if adequate proof is made.[15]

B. *Treaty rights.* As an alternate ground for reversal, Akzo argues that, because the proceedings below discriminated against Akzo on the basis of its Dutch nationality, they violate United States treaty obligations. We disagree with Akzo's premise that there was discrimination here. Essentially, Akzo employs a *non sequitur* to support its position. The core of Akzo's claim is that it was denied the rights that would have been afforded a domestic firm sued for patent infringement in a district court. According to Akzo, this "inferior treatment" by the Commission constitutes discrimination on the basis of nationality. That analysis misses the mark. The appropriate inquiry is whether Akzo was afforded the same rights afforded to domestic firms in a *§337 proceeding* before the *Commission*. Clearly, Akzo has failed to demonstrate that it suffered from discriminatory treatment. First, under the express terms of the protective order, both Akzo and Du Pont were bound by identical procedures regarding confidentiality and discovery. Neither party was allowed access to the other party's confidential business information. Second, the same argument was rejected in *Certain Spring Assemblies and Components Thereof*, Inv. No. 337-TA-88, 216 USPQ 225; *aff'd sub nom. General Motors Corp. v. U.S. International Trade Commission*, 687 F.2d 476, 215 USPQ 484 (CCPA 1982), *cert. denied*, 459 U.S. 1105 (1983). In that case, respondent unsuccessfully raised certain U.S.-Canadian treaties as a defense to enforcement of §337. The Commission observed:

> Section 337 does not discriminate against foreign corporations by virtue of their foreign status. It applies to foreign and domestic corporations alike. Section 337 gives the Commission jurisdiction over products imported from a foreign country, *even if they are manufactured and/or imported by a U.S. corporation*. The Commission's jurisdiction lies in unfair acts occurring in connection with the importation of goods into the United States or their sale, and it extends to all persons engaged in such unfair acts.

216 USPQ at 231 (emphasis added).

IV. *Other Issues*

In this part we consider four separate issues raised by appellants: (1) whether the Commission properly found that continued importation of Akzo's product would substantially injure or tend to injure Du Pont; (2) whether adjudication of §337 actions by a non-Article III tribunal is unlawful; (3) whether Du Pont's pricing practices (with respect to its aramid products) violate the antitrust laws; and (4) whether Du Pont committed inequitable conduct by infringing Akzo's own patent.

A. *Tendency to destroy or substantially injure.* The ALJ concluded (and we have upheld) that Akzo violated §337(a) by the unlawful importation or sale of certain aramid fibers produced in the Netherlands by means of a process which if practiced in the United States would infringe the Blades '756 patent. Such acts, long considered to be violative of §337, clearly constitute unfair acts for the purposes of the statute. *See, e.g., In re Chain Door Locks*, USITC Pub. No. 770 (Apr. 1976), 191 USPQ 272 (USITC 1976); *In re Von Clemm*, 229 F.2d 441, 108 USPQ 371 (CCPA 1955); *In re Amtorg Trading Corp.*, 75 F.2d 826, 24 USPQ 315 (CCPA), *cert. denied*, 296 U.S. 576 (1935).

However, unfair acts, without more, are legally insufficient to support a finding of a §337 violation. That provision declares unlawful "[u]nfair methods of competition and unfair acts in the importation of articles . . . the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States." Thus, to prove a violation of §337, the complainant must show both an unfair act and a resulting detrimental effect or tendency. *New England Butt Co. v. U.S. International Trade Commission*, 756 F.2d 874, 876, 225 USPQ 260, 261 (Fed. Cir. 1985). As this court recently held in *Textron, Inc. v. U.S. International Trade Commission*, 753 F.2d 1019, 224 USPQ 625 (Fed. Cir. 1985), "section 337 has consis-

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[15] This case differs from *Viscofan S.A. v. U.S. International Trade Commission*, 787 F.2d 544, 552, 229 USPQ 118, 124 (Fed. Cir. 1986), because here (but not in *Viscofan*) the confidentiality problem was directly related to the propriety of the exclusion order. Accordingly, we have reviewed the merits of the confidentiality actions. *See American Telephone and Telegraph Co. v. U.S. International Trade Commission*, 626 F.2d 841, 842, 206 USPQ 111, 112 (CCPA 1980).

:atus. It applies to foreign and do- corporations alike. Section 337 the Commission jurisdiction over :ts imported from a foreign country, *they are manufactured and/or im- by a U.S. corporation.* The Com- n's jurisdiction lies in unfair acts ing in connection with the importa- f goods into the United States or sale, and it extends to all persons ed in such unfair acts.

'Q at 231 (emphasis added).

IV. *Other Issues*

s part we consider four separate ised by appellants: (1) whether the sion properly found that continued ion of Akzo's product would sub- y injure or tend to injure Du Pont; her adjudication of §337 actions by rticle III tribunal is unlawful; (3) Du Pont's pricing practices (with to its aramid products) violate the laws; and (4) whether Du Pont ed inequitable conduct by infringing wn patent.

ndency to destroy or substantially

The ALJ concluded (and we have that Akzo violated §337(a) by the l importation or sale of certain ara- rs produced in the Netherlands by f a process which if practiced in the States would infringe the Blades '756 Such acts, long considered to be of §337, clearly constitute unfair the purposes of the statute. *See, e.g., hain Door Locks*, USITC Pub. No. or. 1976), 191 USPQ 272 (USITC *n re Von Clemm*, 229 F.2d 441, 108 371 (CCPA 1955); *In re Amtorg Corp.*, 75 F.2d 826, 24 USPQ 315), *cert. denied*, 296 U.S. 576 (1935).

ver, unfair acts, without more, are nsufficient to support a finding of a olation. That provision declares un- [u]nfair methods of competition and cts in the importation of articles . . ., ct or tendency of which is to destroy antially injure an industry, efficient- conomically operated, in the United Thus, to prove a violation of §337, plainant must show both an unfair a resulting detrimental effect or y. *New England Butt Co. v. U.S. ional Trade Commission*, 756 F.2d 6, 225 USPQ 260, 261 (Fed. Cir. As this court recently held in *Tex- c. v. U.S. International Trade Com-*, 753 F.2d 1019, 224 USPQ 625 ir. 1985), "section 337 has consis-

tently been interpreted to contain a distinct injury requirement of independent proof." 753 F.2d at 1028, 224 USPQ at 631 (citations omitted); *accord, Corning Glass Works v. U.S. International Trade Commission*, 799 F.2d 1559, 230 USPQ 822 (Fed. Cir. 1986); *Warner Brothers, Inc. v. U.S. International Trade Commission*, 787 F.2d 562, 564, 229 USPQ 126, 127 (Fed. Cir. 1986).

According to *Textron*, "Congress may well have included this separate requirement . . . to insure that the extreme and internationally provocative remedy contemplated [by §337] — exclusion of imports from particular countries — would be implemented only when this is compelled by strong economic reasons." 753 F.2d at 1028-29, 224 USPQ at 631 (citations omitted). It follows that the mere concurrence of an unfair act and some resulting injury is not necessarily sufficient, in itself, to establish a violation of §337. "Congress has directed that the remedy of section 337, involving as it does the act of the sovereign in closing our borders to certain imports, be exercised only in those instances where at least there is proof of a tendency to *substantially* injure the subject industry." *Corning Glass Works v. U.S. International Trade Commission*, 799 F.2d 1559, 1567, 230 USPQ 822, 827 (Fed. Cir. 1986) (emphasis in original).

Not only is an injury determination intimately wed to the particular facts of each case, but also the determination of injury is precisely the type of question which Congress has committed to the expertise of the Commission. Thus, on appeal, our review of an injury determination is limited to deciding whether the Commission's decision is supported by substantial evidence. 19 U.S.C. §1337(c) (1982); 5 U.S.C. §706 (1982); *SSIH Equipment S.A. v. U.S. International Trade Commission*, 718 F.2d 365, 371, 218 USPQ 678, 684 (Fed. Cir. 1983); *General Motors Corp. v. U.S. International Trade Commission*, 687 F.2d 476, 215 USPQ 484 (CCPA 1982), *cert. denied*, 459 U.S. 1105 (1983). In other words, we must decide "whether substantial evidence supports the facts relied on and whether the Commissioner's [sic] determination, on the record, is arbitrary, capricious, or an abuse of discretion." *Corning Glass Works*, 799 F.2d at 1568, 230 USPQ at 828. As we noted in *Corning Glass Works*, "the question of quantum of injury is not one on which it would be appropriate for this court to put forth a legal standard." *Id.* Nor are we allowed to substitute our own judgment for that of the Commission. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Of course, a decision is supported by substantial evidence if it is supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Our review of the record in this case compels the conclusion that the Commission's determination — that Akzo's unfair imports of aramid fibers will have a tendency to injure Du Pont substantially — is supported by substantial evidence. The Commission based its injury determination on a prediction of the future effect of Akzo's unfair imports on the domestic industry. There is substantial support for this determination. The record reflects Akzo's intent and capacity to enter the United States aramid fibers market, Du Pont's resulting loss of revenue, and a probable price reduction by Du Pont in response to Akzo's entry into the United States market. Nonetheless, Akzo urges this court to overturn the Commission's exclusion order and deny relief to Du Pont. Akzo first contends that its projected share of the U.S. market during the remaining life of the '756 patent is *de minimis*. It would be both unwise and improper for this court to establish some arbitrary market-share benchmark as a prerequisite to a finding of a §337 violation and we decline to do so. It is sufficient that the record supports the Commission's conclusion that, upon entry into the U.S. market, Akzo will capture a significant share of the domestic market, if not in relative percentage figures than certainly in absolute dollar figures.

[3] Second, Akzo maintains that, notwithstanding its entry into the market, Du Pont's aramid fibers sales volume, revenues and profits will all increase during the remaining life of the patent. But Akzo mischaracterizes the proper standard for measuring injury. The issue is not whether Du Pont's sales, revenues and profits will increase beyond their 1985 levels but rather whether Akzo's presence in the market will substantially injure Du Pont's business during the 1986 - 1990 period (the remaining life of the Blades '756 patent).

As Du Pont correctly points out, nothing in §337 requires a showing that the domestic industry will be utterly deprived of profitability. "Where the unfair practice is the importation of products that infringe a domestic industry's . . . patent right, even a relatively small loss of sales may establish, under section 337(a), the requisite injury . . . ." *Bally/Midway Mfg. Co. v. U.S. International Trade Commission*, 714 F.2d 1117, 1124, 219 USPQ 97, 102 (Fed. Cir. 1983). This proposition is entirely consistent with the legislative history of §337. In a House

Report discussing the application of §337 to unfair competition involving patent infringement, Congress stated: "Where unfair methods and acts have resulted in *conceivable losses of sales*, a tendency to substantially injure such industry has been established." *See* House Comm. on Ways and Means, Trade Reform Act of 1973, H.R. Rep. No. 571, 93d Cong. 1st Sess.78 (1973) (emphasis added); *accord In re Von Clemm*, 229 F.2d 441, 445, 108 USPQ 371, 374 (CCPA 1955).

Because substantial evidence supports the facts relied upon by the Commission in making its determination that Akzo's unfair imports would tend to injure Du Pont substantially, we must affirm its injury determination. Akzo has failed to demonstrate that the commission's determination is arbitrary, capricious, or an abuse of discretion.

A contrary result would emasculate the protections of §337 with respect to high technology ventures. Typically, in high technology industries, acute competition forces competitors to commit substantial resources to research and development in hopes of generating profits before either their patents expire or before technological advance makes the products obsolete. Thus, innovators frequently resign themselves to losses during the early life of their patents with the expectation that, if product development and marketing efforts are successful, profits earned during the later life of other patents will provide sufficient compensation for their endeavors.

On this record, Du Pont's aramid fibers industry can be said to furnish a classic illustration. Although Du Pont has undertaken extensive product development and marketing efforts since 1973, the company had not earned any return on its investment through 1984. Du Pont anticipates that it will realize its first positive net operating earnings from its aramid fibers production in 1985.

In reaching its injury determination, the Commission permissibly recognized that the aramid fibers industry is in transition from a period requiring extremely high investment of resources to a period when the industry will finally realize a return on that investment. In these circumstances, diminished profits, lower return on investment, and reduced sales are all indicative of substantial injury.

[4] *B. Adjudication of §337 actions by a non-Article III tribunal.* Apparently employing the "kitchen sink" or "let's try anything" approach to appellate advocacy, Akzo raises an additional challenge to the Commission's proceedings. Relying primarily on *Northern Pipeline Construction Co. v. Marathon Pipe Line Co.*, 458 U.S. 50 (1982), Akzo characterizes the current §337 proceedings as "inherently judicial" involving "essentially private rights" and concludes that the Constitution requires adjudication of §337 issues by Article III courts. Both Akzo's premise and conclusion are flawed. Although it is true that private rights may be affected by §337 determinations, the thrust of the statute is directed toward the protection of the public interest from unfair trade practices in international commerce. As this court recognized in *Young Engineers, Inc. v. U.S. International Trade Commission*, 721 F.2d 1305, 1315, 219 USPQ 1142, 1152 (Fed. Cir. 1983), a §337 proceeding "is not purely private litigation 'between the parties' but rather is an 'investigation' by the Government into unfair methods of competition or unfair acts in the importation of articles into the United States." Moreover, "[t]he power to regulate commerce with foreign nations is expressly conferred upon Congress, and being an enumerated power is complete in itself, acknowledging no limitations other than those prescribed in the Constitution." *Buttfield v. Stranahan*, 192 U.S. 470, 492 (1904). Properly viewed, §337 and its predecessor provisions represent a valid delegation of this broad Congressional power for the public purpose of providing an adequate remedy for domestic industries against unfair practices beginning abroad and culminating in importation. *Sealed Air Corp. v. U.S. International Trade Commission*, 645 F.2d 976, 985–86, 209 USPQ 469, 478 (CCPA 1981).

C. Du Pont's pricing practices. Under Du Pont's value-in-use pricing program, the price at which Du Pont sells aramid fibers varies in accordance with the particular end-use to which the purchaser puts the product. Although Du Pont's customers may use the aramid fibers for whatever purpose they desire, they are required to pay Du Pont the price appropriate to the ultimate end-use. To that objective, Du Pont requires its customers to agree that they will use the aramid fibers for the specific end-use for which they are purchased or, if the aramid fibers are put to a different end-use or are resold, that they will pay Du Pont an amount representing the difference between the initial purchase price and the price for the ultimate end-use.

According to Akzo, each such agreement constitutes a "contract . . . in restraint of trade," and the entire pattern of agreements, policing and surveillance constitutes a "combination . . . in restraint of trade" within the

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meaning of §1 of the Sherman Act. Although the Commission specifically found that the adoption of Du Pont's value-in-use pricing strategy reflects price competition with other substitute products for various end uses," Akzo continues to argue that Du Pont's value-in-use pricing for aramid fibers violates the antitrust laws.

Plainly, value-in-use pricing is not *per se* an anticompetitive restraint on trade within the meaning of the antitrust laws. In *Carter-Wallace, Inc. v. United States*, 449 F.2d 1374, 171 USPQ 359 (Ct. Cl. 1971), one of this court's predecessor courts sustained against an antitrust challenge a pricing system in which purchasers paid a lower price for the drug meprobamate when used in certain combination drugs. The court noted that "the vendee firms, if one looks at their business as a whole, are not prohibited or deterred from making any use they wish of the meprobamate." *Id.* at 1379, 171 USPQ at 362. Moreover, "[i]t is even reasonable to assume, nothing else appearing, that if the vendees change their minds after purchasing the drug at the lower price they can make unrestricted use of it by paying the difference between that lower price and the consent-decree price." *Id.* at 1379 n.4, 171 USPQ at 362 n.4.

Similarly, under Du Pont's value-in-use pricing system, its customers may use their aramid fibers for whatever purpose they desire, including resale, providing they pay Du Pont the price appropriate to the ultimate end-use. Contrary to Akzo's position that Du Pont's pricing system is anticompetitive and an unreasonable restriction on use and resale, the Commission found and the record establishes that Du Pont's value-in-use pricing has the procompetitive effect of increasing the volume of aramid fibers that are sold.

Akzo also claims that the ALJ erred in not making specific findings on market definition. But, as this court recently observed, the trier of fact need not engage in the meaningless exercise of market definition where no wrongful conduct has been shown. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 875, 228 USPQ 90, 100 (Fed. Cir. 1985). Equally groundless is Akzo's contention that the ALJ erred by not shifting to Du Pont the burden of demonstrating that its pricing policies had procompetitive effects. The Supreme Court, in *National Collegiate Athletic Ass'n v. Board of Regents*, 468 U.S. 895 (1984), made abundantly clear that the burden of proof shifts only where the evidence shows that the challenged practice has the "hallmarks of anticompetitive behavior," namely, that it has operated to raise prices and reduce output. *Id.* at 113. Conversely, in this case, the evidence establishes and the Commission found that the alleged "restraint," value-in-use pricing, results in reduced prices and increased output.

D. *Du Pont's alleged inequitable conduct in manufacture.* During the proceedings below, Akzo asserted that Du Pont infringed Akzo's U.S. patent 4,308,374 ('374) patent) on a polymerization solvent system used in the formulation of the polymer which is spun into aramid fibers by means of the Blades '756 process. Notwithstanding §337(c) of the Tariff Act of 1930 which provides that "[a]ll legal and equitable defenses may be presented," the ALJ struck Akzo's equitable defense and refused to hear the underlying evidence. On appeal, Akzo contends that the ALJ thus denied Akzo the opportunity to establish a meritorious defense to Du Pont's §337 claim. For two reasons we disagree that this defense was meritorious.

Our conclusion is first supported by the recent decision of the District Court for the Eastern District of Virginia holding the '374 patent invalid for obviousness under 35 U.S.C. §103. *Akzo N.V. v. E.I. DuPont de Nemours & Co.*, Civil Action No. 85-0459-R (E.D. Va. April 24, 1986), on appeal to this court, No. 86-1327/1358.[16] Under that decision, Akzo's infringement claim has been adversely decided and Du Pont has a legal right to do the act claimed to be infringing. Consequently, there is as yet no legitimate basis for Akzo's equitable defense. *See Young Engineers, Inc. v. U.S. International Trade Commission*, 721 F.2d 1305, 1315-16, 219 USPQ 1142, 1152 (Fed. Cir. 1983). Second, this same result is compelled in this instance by this court's decision in *SSIH Equipment S.A. v. U.S. International Trade Commission*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983). In *SSIH*, we held that allegedly "inequitable conduct" is not a defense to a §337 action where the conduct occurred after issuance of the complainant's patent and involved a different patent. *Id.* at 378-79, 218 USPQ at 689-90. In this case, Du Pont's '756 patent was issued in 1973 and pertains to a spinning process; Akzo's '374 patent was issued in 1981 and pertains to a polymerization process.

Conclusion

For these reasons, we affirm the Commission's exclusion order prohibiting the impor-

[16] That appeal was argued on November 7, 1986 before the same panel of judges as heard the current appeal.

tation into the United States of aramid fibers manufactured by Akzo in the Netherlands.

AFFIRMED.

Court of Appeals, Ninth Circuit

Lifshitz v. Walter Drake & Sons Inc., et al.

Nos. 85-6087 and 85-6130

Decided December 30, 1986

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Motions (§410.31)

F.R.Civ.P. 50(b)'s requirement that motion for judgment notwithstanding verdict be brought only if party has moved for directed verdict at close of evidence is not satisfied by defendant's motion in limine which, in seeking dismissal of plaintiff's unfair competition claims, was brought prior to trial but not ruled upon until after close of evidence, which was limited to claim that court lacked jurisdiction to entertain common law unfair competition claims based on alleged copying, and which did not address additional unfair competition issues, since issue of sufficiency of evidence on unfair competition claims was not placed squarely before district court, and thus such motion was not enough like motion for directed verdict so as to satisfy requirements of rule.

COPYRIGHTS

2. Notice, deposit and registration — Notice — Omission of or error in notice (§207.0305)

Copyright Act's exception, 17 USC 405(a)(1), for distribution of "relatively small" number of copies of work from which copyright notice has been omitted, does not apply in case where party began adding copyright notice with date more than one year after year in which first publication occurred, since all copies of such work, numbering approximately 15,000, are deemed by 17 USC 406(b) to have been published without notice.

3. Notice, deposit and registration — Notice — Omission of or error in notice (§207.0305)

Copies of product not bearing copyright notice that were in hands of distributor had not yet been "distributed to the public" as called for by 17 USC 405(a)(2), and thus party asserting copyright should have made efforts to remedy notice on such copies.

4. Notice, deposit and registration — Notice — Omission of or error in notice (§207.0305)

"Substantial compliance rule," which has been applied under 1909 Copyright Act to bar willful infringers from asserting errors in copyright notice as defense, should not be applied to significantly different statutory scheme of 1976 Copyright Act.

Appeal from District Court for the Central District of California, Keller, J.

Actions by Igor Lifshitz against Walter Drake & Sons Inc., and Etna Products Co. Inc. for trademark infringement, unfair competition, fraud, conspiracy, copyright infringement, and intentional infliction of emotional distress. From judgment in part for plaintiff, defendant Etna and plaintiff appeal. Affirmed.

Kathryn Tschopik, Los Angeles, Calif., and Robert C. Faber, New York, N.Y., for appellant.

Clinton T. Bailey, Beverly Hills, Calif., for appellee Lifshitz.

Before Wallace, Boochever, and Kozinski, Circuit Judges.

Wallace, Circuit Judge.

Etna Products Co., Inc. (Etna) appeals from the district court's denial of its motion for a judgment notwithstanding the verdict (j.n.o.v.) or for a new trial on Lifshitz's unfair competition claim. Etna also contends that the district court erred in denying its motion for a new trial because of improper instruction to the jury regarding Lifshitz's unfair competition claims, and in improperly excluding certain evidence. Lifshitz cross-appeals from the entry by the district court of a j.n.o.v. on Lifshitz's copyright claim. The district court had jurisdiction under 28 U.S.C. §§ 1332 and 1338(b). We have jurisdiction pursuant to 28 U.S.C. § 1291, and we affirm.

I

Lifshitz, a native of the Soviet Union who emigrated to the United States in 1975,

As articulated in its discussion above, the Court believes that plaintiffs have established a likelihood of success on the merits. At the very least, however, plaintiffs have surely raised sufficiently serious questions going to the merits to make them a fair ground for litigation.

III. *Balance of Hardships*

The final element required for granting a preliminary injunction is a finding that the balance of hardships tips decidedly in favor of the party seeking the injunctive relief. Based on the affidavits and testimony, the Court concludes that this standard is met, in that the balance of hardships in this case tips decidedly in favor of New Line. Of significance to the Court's decision is that this month marks the premiere of Nightmare IV. This premiere is being accompanied by a massive advertising and promotional campaign, including the release of the Fat Boys video. Tr. at 13. It is in this month that many individuals will make their decision whether Nightmare IV is a film that they are interested in viewing. Thus, the telecast of the lower quality D.J. Jazzy Jeff video with the somewhat silly and less frightening Freddy could dissuade an unspecified number of individuals from seeing the film.

Moreover, the Court believes that Zomba will not be significantly harmed if they are forced to wait a few months before being able to release their music video. The Court has every intention of having this matter tried without significant delay and will place the parties on an expedited discovery and pretrial order track. Although Zomba might be financially better off if they were permitted to release the music video now and thereby obtain the benefits of New Line's massive promotional campaign, the Court believes that Zomba is not entitled to this benefit, particularly because it would result in unjust enrichment of Zomba at New Line's expense.

Finally, a failure to grant an injunction now will essentially be denying New Line ultimate relief, because once the D.J. Jazzy Jeff music video is released on MTV the injury to Nightmare IV and to the sale of "Are You Ready for Freddy?" will be irreparable. On the other hand, a slight delay in the release of the D.J. Jazzy Jeff music video will not result in significant harm to Zomba.

CONCLUSION

Inasmuch as New Line has adequately demonstrated irreparable injury, that the case presents sufficiently serious questions going to the merits to make them a fair ground for litigation, and that the balance of hardship is on its side, New Line's motion for a preliminary injunction is granted.[12] Zomba is enjoined from manufacturing, advertising, distributing, selling or releasing for public broadcast, telecast or other exhibition, the music video entitled "A Nightmare on My Street," performed by D.J. Jazzy Jeff, during the pendency of this action. The parties are directed to complete discovery by September 30, 1988 and file a joint pretrial order by October 21, 1988.

Settle preliminary injunction on notice.

Court of Appeals, Federal Circuit

Smithkline Diagnostics Inc. v. Helena Laboratories Corp.

Nos. 87-1532 and -1533

Decided October 12, 1988

PATENTS

1. Patent construction — Claims — Defining terms (§125.1305)

Claim limitation, for specimen test slide and method for detecting occult blood in fecal matter, specifying that catalyst of positive monitor is "a compound that reacts to environmental conditions in a manner similar to hemoglobin," must be read to include hemoglobin itself.

Broadcasting System, 503 F.Supp. 1137, 1146 [208 USPQ 580, 587] (S.D.N.Y. 1980), *aff'd*, 672 F.2d 1095 [215 USPQ 289] (2d Cir. 1982) (defendants were guilty of bad faith where plaintiffs denied permission to use copyrighted material because they were using it themselves and defendants used material anyway).

In addition, the Court believes that the fact that Zomba sought an opinion of counsel with respect to their Freddy does not necessarily indicate good faith because counsel was apparently not asked to consider the issue of whether the planned video or music infringed the Nightmare series but only whether the Freddy character (which Zomba apparently told the law firm was called "Teddy") was infringing.

[12] Having granted New Line's motion for a preliminary injunction under the copyright law, the Court need not consider New Line's arguments for an injunction under the Lanham Act.

2. Patentability/Validity — Obviousness — In general (§115.0901)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Appellate review of federal district court's factual findings underlying its conclusion on obviousness is governed by clearly erroneous standard, although conclusion of obviousness or non-obviousness is reviewed as matter of law.

PATENTS

3. Patentability/Validity — Obviousness — Relevant prior art (§115.0903)

Patent infringement defendant which alleges invalidity due to obviousness cannot pick and choose among individual elements of assorted prior art references to recreate claimed invention, but rather must show some teaching or suggestion in references to support their use in particular claimed combination.

4. Patentability/Validity — Inventorship (§115.13)

35 USC 116, as amended in 1984, which authorizes joint inventorship even if named inventors did not jointly invent every claim, applies to patent even though patent was in litigation on date of statute's enactment and even though 35 USC 106(e) specifies that parties in cases pending on date of enactment shall have their rights determined on basis of "substantive law" in effect prior to date of enactment, since "all claims" rule, which requires inventorship entity to be true origin of every claim in patent, was not uniformly accepted as "substantive law" before 1984 amendments.

5. Infringement — Defenses — Estoppel (§120.1103)

Patent infringer that marketed slides for detecting occult blood in fecal matter with non-infringing lead acetate but that failed to alter package insert stating that slides contained hemoglobin, which is infringing, is not estopped from denying that slides contained hemoglobin, and thus cannot be said to have committed "infringement by estoppel," since admittedly non-infringing product cannot be converted by estoppel into infringing product.

6. Patentability/Validity — Fraud or inequitable conduct (§115.15)

Lack of any evidence of patentee's actual wrongful intent or gross negligence precludes finding of inequitable conduct, since such evidence, although it need not be direct but may be inferred from patentee's conduct, is required for finding of inequitable conduct.

Particular patents — Chemical — Specimen test slides

4,365,970, Lawrence and Townsley, specimen test slide for detecting hidden or invisible (occult) blood in fecal matter and thereby for early diagnosis of gastroentrological diseases including colorectal cancer, and method improvement of built-in verification controls, claims 1, 2, 4, and 5 valid, infringed as to defendant's product containing hemoglobin but not infringed as to defendant's product containing lead acetate.

Appeal from the U.S. District Court for the Eastern District of Texas, Fisher, J.

Patent infringement action brought by Smithkline Diagnostics Inc. against Helena Laboratories Corp. From federal district court ruling holding patent valid but not infringed, parties cross-appeal. Affirmed in part on modified grounds, reversed in part, and remanded.

Donald Dunner, of Finnegan, Henderson, Farabow, Garrett & Dunner, Washington, D.C. (Allen M. Sokal, Washington, D.C., on brief; Alan D. Lourie and Stuart R. Suter, Philadelphia, Pa., of counsel), for plaintiff-appellant.

Jerald I. Schneider, of Cullen, Sloman, Cantor, Grauer, Scott & Rutherford (Charles R. Rutherford, with them on brief), Detroit, Mich., for defendant/cross-appellant.

Before Nichols, senior circuit judge, and Rich and Nies, circuit judges.

Nies, J.

SmithKline Diagnostics, Inc. (SKD) appeals the final judgment of the United States District Court for the Eastern District of Texas, *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 662 F.Supp. 622 (E.D. Tex. 1987), holding United States Patent No. 4,365,970 ('970) valid as between the parties but not infringed by either of two accused products of Helena Laboratories Corp. Based on its holding of noninfringement, the court dismissed SKD's complaint. SKD appeals the findings of noninfringement. In a cross appeal, Helena asserts that if the judgment of noninfringement is not affirmed, this court should re-

verse the judgment that the asserted claims are not invalid for obviousness. Helena also asserts error in that the court did not uphold other pleaded defenses or its counterclaim for unfair competition, matters on which the court made no explicit findings or conclusions.

We affirm the judgment of validity, but on different grounds from those stated by the district court. On the issue of infringement, we affirm the finding that Helena's product containing lead acetate does not infringe the asserted claims but reverse with respect to Helena's product containing hemoglobin. Helena has failed to persuade us that the record shows triable issues on the other matters raised in its cross appeal. Thus, we affirm-in-part on modified grounds, reverse-in-part, and remand for calculation of damages.

I
BACKGROUND

SKD owns the '970 patent, issued to two of its employees, Dr. Paul Lawrence and Charles Townsley, on December 28, 1982. The patent covers a specimen test slide and method for detecting occult (hidden or invisible) blood in fecal matter, an early symptom of a variety of gastroenterological diseases including colorectal cancer. More specifically, the test slide contains a piece of paper impregnated with a colorless compound, guaiac, which turns blue in the presence of a developing solution, such as hydrogen peroxide, and a catalyst, such as hemoglobin in the blood. Thus, a blue color indicates blood is present, a "positive" result; the absence of blue, a "negative" result, indicates the absence of blood. In practice, a patient places fecal samples on each of several designated test areas on the slide and returns the slide to his physician or a laboratory for testing. To test, a developing solution is place on the test areas, and the areas are observed for color. This much of the subject invention is in the prior art. *See* United States Patent No. 3,996,006 (issued to Pagano on Dec. 7, 1976).

It is important to verify that the guaiac paper and developing solution are working properly. If either the paper or solution has lost effectiveness, a false negative result may occur, failing to detect the presence of existent cancer. Conversely, if the paper or solution becomes contaminated, a false positive test may occur, causing patient anxiety and unnecessary clinical investigations. To ensure accuracy, separate materials (external controls) were sold which could be used to check that the paper and solution were actually working. The parties dispute whether external controls consisted only of a representative unused slide from a batch of slides or also included a slide having three test areas with only one area being used for the fecal smear, the others for testing performance of the product. There is no dispute, however, that in either case the control was not built into the slide.

The invention of the '970 patent improves on the Pagano test slide and separate verification controls by providing built-in positive and negative monitors separate from the test areas. The positive monitor contains (i.e., is printed with) a catalyst, which must be a compound that reacts to environmental conditions in a manner similar to hemoglobin. The negative monitor lacks the catalyst; thus, it consists of the guaiac-laden paper alone. In practice, developing solution is added to the two monitors after it is applied to the fecal test areas. A blue color on the positive monitor indicates that the paper and solution are working. The absence of blue on the negative monitor assures that the slide has avoided contamination.

SKD asserts that independent device claim 1, claims 2 and 4 which depend from claim 1, and independent method claim 5 of the '970 patent are infringed.[1] Claims 1 and 5, the only independent claims asserted, both contain the limitation that the catalyst of the positive monitor is "a compound that reacts to environmental conditions in a manner similar to hemoglobin." Whether that claim limitation, as properly interpreted, excludes hemoglobin itself is critical, as we shall see, to the issues of validity and infringement.

When the '970 patent issued in December of 1982, SKD was marketing a slide, under the trademark HEMOCCULT, which contained hemin as the catalyst. At that time, Helena had competitive slide products on the market, sold under its COLOSCREEN mark, which used hemoglobin as the catalyst in a positive test monitor. Later, in April of 1984, Helena changed to use of lead acetate rather than hemoglobin as the positive monitor's catalyst. Until November 1985, however, Helena continued to enclose literature in its slide packages stating that the positive monitor contained hemoglobin.

SKD asserted infringement of the '970 claims, both literally and under the doctrine of equivalents, by the Helena products containing hemoglobin. With respect to Helena's lead acetate product, SKD asserted that Helena should be estopped to deny that its product contains hemoglobin because it continued to indicate that the product contains hemoglobin after the change was made to lead acetate. SKD did not assert that the lead acetate product would be covered by the claims but for the misrepresentation.

Helena contended that its products containing hemoglobin do not infringe because the claim language "similar to hemoglobin" literally excludes hemoglobin itself, and that the prosecution history precludes interpreting the claim to cover a hemoglobin product. Helena also asserted that the '970 claims in issue are invalid as obvious within the meaning of 35 U.S.C. §103 (1982), and invalid under 35 U.S.C. §116 (1982) for failure to name the proper inventors. In addition, Helena asserted the defense of inequitable conduct and raised an unfair competition counterclaim.

The district court interpreted the claim limitation at issue as excluding hemoglobin itself. Based upon that interpretation, the court found the invention of the '970 patent nonobvious. Had the claims covered hemoglobin, however, the court stated that the claim would have been invalid as obvious over prior art disclosing hemoglobin as a catalyst in positive test monitors.

Under its interpretation of the claim limitation "similar to hemoglobin" recited in claims 1 and 5, the court found Helena's hemoglobin-containing slides noninfringing, either literally or under the doctrine of equivalents. It rejected SKD's estoppel argument with respect to Helena's products containing lead acetate. It further held that, if Helena were found to infringe, the infringement was not willful, an issue not appealed.

Neither in its judgment nor in its findings of fact and conclusions of law did the district court mention Helena's other defenses or its counterclaim for unfair competition. Both parties have appealed, each asserting error in certain findings and conclusions made adverse to them, and each raising various arguments concerning issues not explicitly ruled on by the court.

II
OPINION

A. *Claim Interpretation*

The claims of the '970 patent measure the invention at issue; thus, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses. *See, e.g., SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121, 227 USPQ 577, 585 (Fed. Cir. 1985) (in banc). To ascertain the meaning of the claims, we look to the claim language, the specification, and the prosecution history. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1579, 6 USPQ2d 1557, 1560 (Fed. Cir. 1988); *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir. 1985). Also relevant are the other claims and expert testimony. *See, e.g., Perini America, Inc. v. Paper Converting Mach. Co.*, 832 F.2d 581, 584, 4 USPQ2d 1621, 1624 (Fed. Cir. 1987). Moreover, the claims should be construed as one skilled in the art would construe them. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988).

This court reviews a district court's claim interpretation as a matter of law, unbridled by the constraints of the "clearly erroneous" standard of review. That interpretation may

[1] The '970 patent claims asserted to be infringed are:

1. In an occult blood specimen test slide having a front panel, a rear panel, said front panel having one or more openings, sheet means carrying a test reagent between the front and rear panels underlying each of said openings, a hinged cover adapted to overlie a portion of the front panel and said openings and flap means in the rear panel opposite said openings and pivotable to expose the underside of the sheet, the improvement comprising: an area positioned on a portion of the sheet means facing the rear panel and isolated from the openings in the front panel, said area including a positive and negative monitor, said positive and negative monitors including the test reagent and said positive monitor additionally including a compound that reacts to environmental conditions in a manner similar to hemoglobin.

2. The slide of claim 1 in which the compound in the positive monitor is a blood component and the test reagent is guaiac.

4. The slide of claim 2 in which the positive and negative monitors are framed by a brightly colored inert border.

5. In a method for determining the presence of occult blood in a specimen test slide having a guaiac treated specimen receiving sheet between a front panel and a rear panel with openings in the front and rear panels and pivotable covers to cover said openings which consists of smearing fecal matter onto the guaiac sheet through an opening of the front panel and applying a developing solution to the guaiac sheet at the corresponding opening in the rear panel the improvement which comprises further applying the developing solution to an area positioned on a portion of the sheet facing the rear panel and isolated from he openings in the front panel, said area including a positive and negative monitor, said positive and negative monitors including the guaiac and said positive monitor additionally including a compound that reacts to environmental conditions in a manner similar to hemoglobin.

depend, as here, however, on evidentiary material which requires resolution of factual issues, such as what occurred during the prosecution history. *See, e.g., ZMI Corp.*, 844 F.2d at 1578, 6 USPQ2d at 1559; *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054, 5 USPQ2d 1434, 1441 (Fed. Cir. 1988); *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1021, 4 USPQ2d 1283, 1286 (Fed. Cir. 1987). We review resolution of those factual issues under the clearly erroneous standard. *See, e.g., Perini America*, 832 F.2d at 584, 4 USPQ2d at 1624.

The dispute in this case centers on the meaning of the claim limitation "including a compound that reacts to environmental conditions in a manner similar to hemoglobin," which appears in independent claims 1 and 5 and is, of course, a limitation in dependent claims 2 and 4. Helena argues, and the district court concluded, that the phrase must be interpreted to exclude hemoglobin itself. On the other hand, SKD contends that the phrase encompasses hemoglobin as well as other similar materials. We turn to the sources useful in claim interpretation to resolve this dispute.

1. *The Claim Language*

The first requirement in claim interpretation is to examine the claim language. *ZMI Corp.*, 844 F.2d at 1579, 6 USPQ2d at 1560; *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 672, 221 USPQ 944, 948 (Fed. Cir.), *cert. denied*, 469 U.S. 1037 (1984). Helena argues that the "ordinary" meaning of "similar to" excludes "identical." Although that argument has a superficial logic, we cannot agree, in the context of these claims, that the phrase "similar to hemoglobin" necessarily excludes hemoglobin.

In finding that the claims exclude hemoglobin, the district court relied upon the statement of one co-inventor, Dr. Lawrence. In a report on his work, Dr. Lawrence had written that "the stabilities of the proteins [such as hemoglobin] are too short to be compatible with standard dating of HEMOCCULT slides."[2] The district court took that statement to indicate Dr. Lawrence's belief that hemoglobin would not work. 662 F.Supp. at 628.

Taken in context, however, Dr. Lawrence's statement does not indicate that he believed hemoglobin would not work at all, as shown in the following additional excerpts from the report:

> A variety of catalysts may be printed: for example, . . . Fe/protopurphyrin (hemin); homo proteins such as hemoglobin (Hb) . . . may be similarly used.
>
> Printing of proteins such as Hb . . . presents practical difficulties. High concentrations are required . . . . More important, once printed the stabilities of the proteins are too short to be compatible with standard [three year] dating of Hemoccult(R) slides. . . .
>
> . . . .
>
> [H]emin spots have a dated stability comparable or greater than Hemoccult(R) slides.

Nowhere does Dr. Lawrence state that hemoglobin *cannot* be used. The thrust of his analysis is a justification for his preference for hemin over other alternatives, inasmuch as it had sufficient stability to meet the standard three-year dating period. In fact, Dr. Lawrence states that hemin and hemoglobin "may be similarly used." Moreover, he testified at trial that hemoglobin would work and that methods were known for stabilizing hemoglobin, one of the problems he noted as a reason why hemin works better. In any event, the claim does not contain a limitation with respect to the duration of the catalyst's effectiveness.

We cannot conclude that the claim language indicates what characteristics the catalyst must have. The limitation at issue does not identify specific catalysts to be included or excluded. Viewed in this manner, the limitation does not exclude hemoglobin; rather, it reflects the fact that a compound similar to hemoglobin may work better than hemoglobin itself.

2. *Specification*

The limitation need not be given a more restrictive meaning in the claims of the '970 patent by reason of the specification. The specification of the '970 patent shows a clear intent by the inventors to include hemoglobin when they claimed their invention. It states:

> Since guaiac-based fecal occult blood tests are actually testing for the catalytic activity of hemoglobin in blood, the *positive monitor should employ either hemoglobin or a catalyst which would react to adverse environmental conditions in a manner similar to hemoglobin. Preferably,* the test slide of this invention employs *hemin,* a hemoglobin derived catalyst, as the catalyst in the positive monitor.

'970 Patent Specification, col. 4, ln. 1-8 (issued Dec. 28, 1982) (emphasis added).

[2] Record of Invention, SKD, Case No. 14084, at 1 (March 12, 1981). By "instability," Dr. Lawrence referred to the tendency of catalytic compounds to decay over time.

Thus, the specification specifically discloses hemoglobin and hemin, with the latter preferred, as compounds to be used in the positive monitor. We agree with SKD that it would be a strained interpretation to exclude hemoglobin from the claims when the specification specifically discloses it as a viable candidate for the positive monitor catalyst.

Helena offers a convoluted argument to overcome the specification's disclosure of hemoglobin as a catalyst. The argument begins with the premise that the '970 patent described two functions for the monitor: testing both for proper functioning of the chemicals (guaiac and developer) and for deterioration of the fecal sample caused by the environment. (Other suppliers' slides test only the former and use hemoglobin). Thus, Helena asserts, the patent requires a control that deteriorates in the same way as the blood deteriorates in the fecal sample. Hemoglobin does not deteriorate like blood (note the instability problem Dr. Lawrence related), hence, Helena reasons, the patent claims cannot include hemoglobin. Per Helena, the specification suggests instead that hemin will perform both functions in the positive monitor, as will a compound that "reacts to environmental conditions in a manner similar to hemoglobin" in the blood of the fecal sample.

Helena's argument fails for a number of reasons. Most basic is the fact that neither the claims nor the specification require the positive monitor catalyst to deteriorate like blood in a fecal sample. In addition, the argument ignores entirely the specific disclosure in the specification that hemoglobin is a suitable compound for use as the catalyst. Finally, Helena offers no evidence to show that hemin, which it argues is encompassed by the claims, is relatively more like blood in the fecal samples in terms of deterioration than is hemoglobin.

3. *Prosecution History*

The prosecution history is still another tool useful for claim interpretation. *See, e.g., ZMI Corp.*, 844 F.2d at 1580, 6 USPQ2d at 1561; *McGill Inc.*, 736 F.2d at 673, 221 USPQ at 949. The district court relied most heavily on that tool and determined that, through a claim amendment, the inventors had narrowed the claims to exclude hemoglobin.

The claim limitation at issue was not present in the original claims as filed with the United States Patent and Trademark Office (PTO). Instead, claim 1 provided "the improvement comprising: a control area having a positive and a negative monitor said control area positioned on a portion of the sheet." The Examiner rejected the claims as obvious under 35 U.S.C. §103 (1982), citing United States patents to Pagano (3,996,006) and Friend (4,175,923).

Friend discloses a "throw-in-the-bowl" type of test product made of paper impregnated with guaiac. A section of the paper also has impregnated a blood component (forming a built-in positive monitor). The user sprays the entire paper sheet with developer and first observes it to confirm that the guaiac chemical is working properly. Proper functioning is assured if the part of the paper impregnated with blood component turns blue. The user then drops the product into a toilet bowl containing fecal matter, where the remainder of the paper will turn blue if the fecal matter contains blood or will remain white, indicating the absence of blood.

The Examiner maintained that it would have been obvious from the teaching of Friend to provide positive and negative monitors on the Pagano slide. In response to the First Office Action, on January 25, 1982, the inventors argued that "Friend fails to disclose any negative monitor or control." Thereafter, the Examiner issued a Final Action rejecting the claims as obvious: "Even though Friend is concerned with positive control, it would be obvious to the routineer that both positive and negative controls could be incorporated in Pagano."

The Examiner granted the inventors an interview on July 8, 1982, which the Examiner summarized as discussing the arguments "that areas are not only control but monitors of performance for both false positives and negatives" and "that prior art does not show a negative monitor that indicates false positives." The inventors described the interview, in an Amendment After Final Rejection filed on July 20, 1982, as emphasizing "that Friend fails to disclose any negative monitor or control: . . . The criticality of having a negative monitor present on the occult blood slide was thoroughly discussed at the interview." At this point in the prosecution, neither the Examiner nor the inventors had mentioned the limitation now at issue.

Those parties then conducted a telephone interview on July 27, 1982. In his Summary Record of the conversation, the Examiner states:

> Agreed to amendment of the claims as per Examiner's Amendment (Paper No. 9) to particularly recite the positive and negative monitors.

Paper No. 9 contained the amendment introducing the "similar to hemoglobin" limitation at issue. Following that amendment, the

'970 patent claims were allowed on August 6, 1982.

The district court concluded that the Examiner allowed the patent claims only because of the amendment to overcome the disclosure in the Friend patent. Finding that Friend discloses use of hemoglobin as the positive catalyst, the court determined that the amendment narrowed the claims to avoid that disclosure by excluding hemoglobin from the '970 claims.

Where the district court clearly erred is in its last finding, that the amendment was made to overcome the disclosed use of *hemoglobin* in a monitor. Friend does not specifically disclose or claim a hemoglobin catalyst. Rather, Friend claims "blood" as a substrate or composition for the positive monitor catalyst. Friend's patent specification discloses "commercially available dried human or animal blood" and "components of blood" as the positive catalyst. Consequently, Friend's teaching, although it includes hemoglobin as the catalyst, was not so restricted and an amendment excluding hemoglobin but including hemin (another blood component) would not have overcome Friend's broad disclosure of blood component catalysts.

Thus, we are unpersuaded that the amendment to claim subject matter "similar to" hemoglobin was made to overcome Friend's disclosure of a hemoglobin catalyst. The purpose of the amendment is unclear. SKD reads the Examiner's statement that the amendment was made "to particularly recite the positive and negative monitors" literally and contends that the amendment was made only to satisfy the definiteness requirement of 35 U.S.C. §112 (1982) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."), and not to avoid an obviousness rejection based upon the prior art. We need not determine the purpose for the amendment. We merely hold that the district court's finding, that the amendment was made to overcome Friend's disclosure of a hemoglobin catalyst, is clearly erroneous.

4. *Conclusion*

[1] The district court's findings that the inventor believed hemoglobin would not work and that the claims were amended to exclude hemoglobin disclosed as a catalyst in the prior art are clearly erroneous. We conclude, as a matter of law, that the asserted claims of the '970 patent, properly interpreted, include hemoglobin itself, as well as compounds that react to environmental conditions in a manner similar to hemoglobin, as a positive monitor catalyst.

Because we have determined that the district court improperly interpreted the claims, the remainder of its decisional process on the issues of validity and infringement is distorted. *See, e.g. Panduit Corp.*, 810 F.2d 1561, 1576, 1 USPQ2d 1593, 1603 (Fed. Cir.) ("When the prior art is compared with erroneously interpreted claims, findings of differences between the prior art and the claims will necessarily be clearly erroneous."), *cert. denied*, 107 S.Ct. 2187 (1987); *Moeller v. Ionetics, Inc.*, 794 F.2d 653, 656, 229 USPQ 992, 994 (Fed. Cir. 1986) (improper claim construction can distort entire infringement analysis). Keeping this in mind, we now turn to those issues.

B. *Validity*

1. *Obviousness*

a. *The Standard*

[2] Helena challenges validity of the '970 patent on the grounds that the claimed invention would have been obvious within the meaning of 35 U.S.C. §103 (1982).[3] In evaluating that challenge, the district court properly began its analysis with the presumption that the patent is valid. *See* 35 U.S.C. §282 (1982). That presumption places the burden of proof of facts, and the ultimate burden of persuasion to establish invalidity, on Helena. *See, e.g., Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir.), *amended* 1 USPQ2d 1209 (Fed. Cir. 1986). In reviewing the district court's factual findings underlying its conclusion, we are governed by the clearly erroneous standard. *See, e.g., Panduit Corp.*, 810 F.2d at 1566, 1 USPQ2d at 1595–96. We review the conclusion of obviousness or nonobviousness drawn from the facts so reviewed as a matter of law. *Id.* at 1569, 1 USPQ2d at 1598.

b. *The Factual Inquiries*

Although the district court upheld the validity of the claims in issue, it did so only if

[3] Section 103 provides in relevant part:
A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

the claims were interpreted to exclude hemoglobin. 662 F.Supp. at 626. Having concluded that hemoglobin is within the claims, we can affirm the judgment of validity only if the facts are undisputed or if the court made other findings which lead to that same legal conclusion of nonobviousness despite the claims' coverage of hemoglobin.[4] The latter situation occurs here. The court found that "[t]he '970 patent discloses and claims the *first* fecal occult blood specimen test *slides having built-in positive and negative monitors* for verifying the proper performance of the slide." *Id.* at 624 (emphasis added). The court also made the following findings which are pertinent to the issue of nonobviousness:

> Dr. Lawrence of SKD, a coinventor of the '970 patent, followed a different approach [from that historically taken], namely a [sic] built-in positive and negative controls on each slide. This had the advantage of verifying the performance of every slide and it was much easier to use than external controls. Furthermore, a built-in positive monitor printed during manufacturing gave more reproducible results than external controls that were applied in variable amounts. Dr. Lawrence's approach was also new in that he no longer sought only controls that simulated feces. Monitors that indicated only whether the slide and developer were working properly avoided the confusion that could result from comparing the test results on the actual fecal specimen and on the monitors.

Id. at 625.

The above analysis would lead to a conclusion of nonobviousness even if hemoglobin is the catalyst. The court did not explain why hemoglobin as the positive monitor catalyst changed that analysis, and we see none. Helena maintains that the court erred in not holding the claims invalid, whether or not hemoglobin is the catalyst, because the improvement of placing monitors on a Pagano slide is obvious from the Friend teaching of a positive monitor on the throw-in-the-bowl type of occult blood testing device and method. Given the nature of the Friend product, we cannot agree that the disclosure of a control in Friend (whether positive alone or positive and negative) is a sufficient teaching to make the claimed combination obvious.

[3] Friend explicitly discloses only a positive monitor. Although never mentioned by Friend, if the portions of the paper not impregnated with blood component do not remain white when developer is applied, then product contamination would be indicated. The parties dispute whether that fact amounts to an inherent disclosure of a negative monitor. The asserted "inherent" monitor of Friend's claimed product is the test area itself, however, whereas the claims at issue require control areas which are "isolated from" the test areas on the "rear" of the slide. Merely pointing to a negative monitor in the prior art, which constitutes Helena's main argument to establish obviousness, is unpersuasive. Helena cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention. *See, e.g., Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1481, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 2490 (1987). Helena has the burden to show some teaching or suggestion in the references to support their use in the particular claimed combination. *Uniroyal Inc.*, 837 F.2d at 1051, 5 USPQ2d at 1438–39. A holding that combination claims are invalid based merely upon finding similar elements in separate prior art patents would be "contrary to statute and would defeat the congressional purpose in enacting Title 35." *Panduit Corp.*, 810 F.2d at 1577, 1 USPQ2d at 1605.

Friend's suggestion begins and ends with the disclosure of a built-in control. Nothing in Friend suggests the particular structure or method of the claims, read as a whole. *Id.* (claims, entire prior art, and prior art patents must each be read "as a whole"). The claimed structure positions the monitors on each slide in such a way that the fecal material may contact the slide without contaminating the control areas. *See* '970 Patent Specification at col. 2, ln. 10–18 ("These [monitors] comprise two small areas or spots printed on an isolated area of the guaiac test paper at some distance from the portions of the test paper underlying each of the [two test areas]. In this manner the positive spot

[4] An appellate court may make a finding of fact on evidence that is undisputed. *See, e.g., King v. Commissioner of Internal Revenue*, 458 F.2d 245, 249 (6th Cir. 1972); *Sbicca-Del Mac, Inc. v. Milius Shoe Co.*, 145 F.2d 389, 400, 63 USPQ 249, 260 (8th Cir. 1944); 9 C. Wright & A. Miller, *Federal Practice & Procedure: Civil* §2577 at 699–701 (1971) ("[I]t is settled that findings are not jurisdictional and the appellate court may decide the appeal without further findings if it feels that it is in a position to do so. . . . A remand has been thought unnecessary if all the evidence is documentary or if the facts are undisputed.") (footnotes omitted); *cf. B.D. Click Co. v. United States*, 614 F.2d 748, 755 (Ct. Cl. 1980). An appellate court may also make such a finding even when the evidence is disputed if, as a matter of law, the court could only make one finding of fact or decide the fact in only one way. Otherwise, protracted litigation and unnecessary delay and expense would occur. *B.D. Click*, 614 F.2d at 755.

(monitor) is of such shape and size and placed in such a positive relation to the stool sample(s) that there can be no confusion of its blue color with that of a positive stool sample."). This location provides the advantage that the fecal matter may be conveniently tested at the later time by a laboratory or physician, at which time the monitors will also be activated. *See id.* at col. 3, ln. 38–53 ("To use the slide, the patient . . . applies with an applicator a thin smear of specimen from a portion of his stool on sheet 32 through opening 30 . . . . The cover is then closed . . . . The patient returns the slide either to his physician or a laboratory. The physician or technician [adds] developing solution . . . [and] [t]he test results are then observed.").

Helena also asserts that the claim language is so broad that it would encompass prior art controls in which a blood component for monitoring purposes is not originally on the slide. On the other hand, SKD asserts that the claims require that the monitor must be built into the slide. We agree with SKD.

> The specification states that:
>
> It is still a further object of this invention to provide a simple, rapid, convenient, inexpensive and *built-in control test* which would monitor the test reagents from the date of manufacture to the date of development.

Id. at col. 2, ln. 2–6 (emphasis added). That portion of the specification supports the district court's view that "[t]he '970 patent discloses and claims the first fecal occult blood specimen test slide having built-in positive and negative monitors for verifying the proper performance of the slide." 662 F. Supp. at 624. The claims that the district court was referring to when it stated its view were claims 1 and 5, which require "an area *positioned on* a portion of *the sheet* . . . , said area including a positive and negative monitor." (Emphasis added.) Thus, we agree with the district court's interpretation that the '970 patent claims a test slide having built-in positive and negative monitors. Accordingly, we conclude that, fairly read, the claims cover only slides in which the catalyst is built into the slide itself.

We also agree with the district court that some, but not overwhelming, support for a conclusion of nonobviousness is provided by the objective evidence. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555, 220 USPQ 303, 314 (Fed. Cir. 1983) (Objective evidence of nonobviousness "may in a given case be entitled to more weight or less, depending on its nature and its relationship to the merits of the invention. It may be the most pertinent, probative, and revealing evidence available" on the issue.), *cert. denied*, 469 U.S. 851 (1984).[5]

c. *Conclusion*

After consideration of all of Helena's arguments, we are unpersuaded that the facts established by the record lead to the conclusion that the claims of the '970 patent are invalid under 35 U.S.C. §103. Accordingly, we affirm the district court's judgment of validity, but on different grounds from those stated by that court.

2. *Inventorship*

Helena contends that the '970 patent is invalid because it does not satisfy the requirement that the true inventor or inventors be named.[6] The springboard to that contention is Helena's interpretation of the '970 patent claims as not restricted to built-in control monitors. Using that springboard, Helena asserts that the patent claims match the work done by Lawrence's and Townsley's predecessors at SKD. We agree with the district court, however, that the claims are restricted to built-in monitors. Helena does not contend that Lawrence and Townsley were not the true inventors of the claimed subject matter when the claims are so interpreted.

Helena frames an additional challenge to the '970 patent on the grounds that the named joint inventors did not jointly invent every claim in the '970 patent. SKD does not contest that fact; instead, it relies on the current patent statute, which provides:

> Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

35 U.S.C. §116 (1982) (as amended by the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (1984) (hereinafter, "the Act")). If this section applies to the '970 patent, Helena's challenge fails. We hold that section 116 applies.

The 1984 amendments made a number of substantive changes in the patent statute. Section 106(a) of the Act, *reprinted at* 35 U.S.C. §103 note (Supp. II 1984), states that with certain exceptions "the amendments made by this Act . . . shall apply to all United States patents granted before, on, or after the date of enactment [Nov. 8, 1984]." At least, *prima facie*, the 1984 amendment of section 116 applies to the '970 patent. Helena asserts, however, that it does not apply retroactively because of the exception provided in section 106(e). Section 106(e) states: "[T]he amendments made by this Act shall not affect the right of any party in any case pending in court on the date of enactment to have their rights determined on the basis of the substantive law in effect prior to the date of enactment." This case was pending on November 8, 1984, the date of enactment. The "substantive law" in effect on that date, per Helena, was that a patent was invalid for failure to name proper inventors unless the inventorship entity named was the true origin of *every* claim in a patent containing more than one claim, i.e., the "all claims" rule.

Helena's argument fails because the "all claims" rule was not uniformly accepted as "the substantive law" before the 1984 Act. *Compare In re Sarret*, 327 F.2d 1005, 1010 n.7, 140 USPQ 474, 479 n.7 (CCPA 1964); *In re Hamilton*, 37 F.2d 758, 759, 4 USPQ 224, 227 (CCPA 1930); *Rival Mfg. Co. v. Dazey Prods. Co.*, 358 F.Supp. 91, 101, 177 USPQ 432, 439 (W.D. Mo. 1973); *Stewart v. Tenk*, 32 F. 665, 666 (S.D. Ill. 1887), *with United States v. Telectronics, Inc.*, 658 F.Supp. 579, 592, 3 USPQ2d 1571, 1580 (D. Colo. 1987); *Vekamaf Holland B.V. v. Pepe Benders, Inc.*, 211 USPQ 955, 966–67 (D. Minn. 1981); *SAB Industri AB v. Bendix Corp.*, 199 USPQ 95, 104 (E.D. Va. 1978). The 1984 amendment clearly repudiates the rule. *See generally* 1 D. Chisum, *Patents*, §2.03[3] at 2–25 to –28 (1987).

[4] We do not believe Congress intended, by the exception of section 106(e), to give a litigant a right to invoke the law of a particular circuit on joint inventorship or to preserve a conflict, even for a limited time, between circuits on this issue. Thus, we hold that section 106(e) does not negate the applicability of amended section 116 to the '970 patent and Helena's challenge fails.

C. *Infringement*

1. *Literal Infringement*

This court has repeatedly stated that direct infringement requires a two-step analysis. The claimed invention must first be defined, a legal question of claim interpretation. Second, the trier of fact must determine whether the claims, as properly interpreted, cover the accused device or process. The second step involves a question of fact. *See, e.g. Specialty Composites*, 845 F.2d at 986, 6 USPQ2d at 1603; *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed. Cir. 1984); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). The burden is on SKD, as the patent owner, to prove infringement by a preponderance of the evidence. *See, e.g., Uniroyal, Inc.*, 837 F.2d at 1054, 5 USPQ2d at 1441. Such proof must show that every limitation of the patent claims asserted to be infringed is found in the accused device, either literally or by an equivalent. *See Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935, 4 USPQ2d 1737, 1739–40 (Fed. Cir. 1987) (in banc), *cert. denied*, 108 S.Ct. 1226, 1474 (1988).

We have already performed the first step of the analysis above and have determined that, properly interpreted, independent claims 1 and 5 cover hemoglobin as the positive monitor catalyst.[7] Based upon that interpretation, the second step of the analysis follows without extended commentary. There is no dispute that, before Helena changed its catalyst to lead acetate, Helena's slides contained hemoglobin as the positive monitor catalyst. Moreover, Helena does not contend that its accused product does not embody every other limitation of the asserted claims. Accordingly, any finding other than that the '970 patent claims literally read on Helena's slides containing hemoglobin would be clearly erroneous.

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[5] We need not decide whether, had resolution of the factual inquiries presented a "clear and very strong case of obviousness," *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907, 225 USPQ 20, 25 (Fed. Cir.), *cert. denied*, 474 U.S. 843 (1985), rather than nonobviousness, the objective evidence provided would have outbalanced that case and shown nonobviousness.

[6] The patent statute provides that "whoever invents or discovers" the patentable subject matter "may obtain a patent therefor." 35 U.S.C. §101 (1982).

[7] Having construed the claims one way for determining validity, it is axiomatic that the claim must be construed in the same way for infringement. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1279, 6 USPQ2d 1277, 1280 (Fed. Cir. 1988); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1449, 223 USPQ 603, 610 (Fed. Cir. 1984); *cf. Autogiro Co. of Am. v. United States*, 384 F.2d 391, 399, 155 USPQ 697, 704 (Ct. Cl. 1967) (patentee cannot construe claims narrowly before Patent Office and later broadly before court).

2. *Reverse Doctrine of Equivalents*

A finding that the words of the claims literally read on the accused device does not necessarily end the infringement inquiry. Although SKD has carried its burden and proven that the '970 patent claims asserted read on Helena's hemoglobin-containing slides, Helena may establish the fact of noninfringement by carrying its burden of going forward to show its device "has been so far changed in principle that it performs the same or similar function in a substantially-different way." *SRI Int'l*, 775 F.2d at 1123-24, 227 USPQ at 587; *see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09 [85 USPQ 328, 330-31] (1950). Helena has attempted to carry its burden by pointing to Dr. Lawrence's alleged admission that hemoglobin would not work. Helena's argument, which the district court accepted, 662 F.Supp. at 628, is that Dr. Lawrence's statement indicates hemoglobin operates in a substantially different way from the compounds SKD successfully used as positive monitor catalysts.

As indicated above, Dr. Lawrence never stated that hemoglobin would not work as a catalyst. Claims 1 and 5 of the '970 patent cover compounds that react to environmental conditions in a manner similar to hemoglobin. We have held these claims to include hemoglobin itself as one possible catalyst. Thus, hemoglobin does not operate in a substantially different way from the compounds claimed — which include hemoglobin — and we reject Helena's argument based on the reverse doctrine of equivalents.[8]

3. *Estoppel to Deny Infringement*

With respect to Helena's slides containing lead acetate as the catalyst in the positive monitor, SKD concedes those slides do not infringe the '970 patent either literally or under the doctrine of equivalents. SKD poses, however, a unique "infringement by estoppel" theory. In April 1984, Helena began marketing COLOSCREEN slides containing lead acetate in place of hemoglobin, but failed to alter a package insert stating that the positive monitor contained hemoglobin. The insert was not corrected until November 1985. SKD's theory is that Helena, by incorrectly identifying hemoglobin as the catalyst in the positive monitor, obtained sales to customers who would not otherwise have purchased Helena's product. Had customers known Helena's product did not contain a catalyst similar to the hemoglobin the test was designed to discover, SKD argues, they would not have purchased Helena's product. Having obtained the benefit of such sales, Helena should be estopped, per SKD, from denying that the COLOSCREEN slides marketed between April 1984 and November 1985 contain hemoglobin. Accordingly, because slides containing hemoglobin infringe the '970 patent, the lead acetate slides, per SKD, infringe by estoppel.

The district court rejected SKD's position that these facts establish an estoppel. SKD's theory of estoppel rests on *Crane Co. v. Aeroquip Corp.*, 364 F.Supp. 547, 179 USPQ 596 (N.D. Ill. 1973), *aff'd in part & rev'd in part on other grounds*, 504 F.2d 1086, 183 USPQ 577 (7th Cir. 1974), and its assertion that the case is "completely analogous and should be followed in this case." In *Crane*, Crane licensed Aeroquip to manufacture pipe couplings under the former's patent. Aeroquip then modified its product, which the district court found did not infringe Crane's patent, but continued to place Crane's patent number on its modified couplings. Citing "marking estoppel" cases,[9] the district court found Aeroquip "estopped to deny that it is *liable for royalties* on [the modified] couplings." 364 F.Supp. at 560, 179 USPQ at 606-07 (emphasis added). The Seventh Circuit found that the modified couplings came within the scope of the claims and, thus, expressed "no opinion" on the marking estoppel issue. 504 F.2d at 1093, 183 USPQ at 581.

[5] Whatever the validity of the "marking estoppel" line of cases, we do not find *Crane* applicable to the present case. Helena never took a license under SKD's patent. Accordingly, *liability for royalty* payments is not at issue here. Helena did not place an erroneous patent number on its lead acetate product; it erroneously identified the catalyst used on its product. The district court in *Crane* reached its result, in part, on the reasoning that

> it should be recognized that application of the marking estoppel doctrine in this case should have an important therapeutic function in protecting the public interest. Manufacturers should be on notice that care must be taken in avoiding misrepresentation to the public that goods are protected by a patent.

364 F.Supp. at 560, 179 USPQ at 607. Such reasoning is inapplicable to this case:

> 35 U.S.C. §271(a) provides:
>
> Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent."

Helena's lead acetate product is not the "patented invention" and, therefore, is not an infringement as defined by the statute. We do not accept the proposition that an *admittedly noninfringing* product can be converted by estoppel to an infringing product.

4. *Summary of Infringement Analysis*

Based on properly interpreted claims, Helena's slides which contain hemoglobin literally infringe the asserted claims of the '970 patent. The district court's finding of noninfringement is clearly erroneous, based as it is upon a legally erroneous interpretation of the asserted claims. We reverse that portion of the court's judgment finding noninfringement by Helena's hemoglobin-containing slides. With respect to Helena's slides containing lead acetate as the positive monitor catalyst, however, we agree with the court that SKD failed to carry its burden of proving infringement. Accordingly, we affirm the court's finding of noninfringement as to the lead acetate product.

D. *Inequitable Conduct*

In its cross appeal, Helena contends that the district court erred in failing to hold the '970 patent unenforceable. The grounds for Helena's charge of unenforceability are four alleged breaches of the duty to disclose material information, and to disclose that information accurately, to the PTO during prosecution of the '970 patent. *See* 37 C.F.R. §1.56 (1987). Such a breach may constitute inequitable conduct sufficient to render a patent unenforceable. *See, e.g., J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822 (1985); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362-63, 220 USPQ 763, 773 (Fed. Cir.), *cert. denied*, 469 U.S. 821 [224 USPQ 520] (1984).

Having found no infringement, the district court apparently did not consider it necessary to reach the question of enforceability. Because we reverse the finding of noninfringement, the defense of inequitable conduct must be considered. When the pertinent facts are undisputed, as here, an appellate court need not remand for the trial court to make findings and conclusions but may resolve the issue. *See, e.g., Icicle Seafoods, Inc. v. Worthington*, 475 U.S. 709, 714 (1986); *UMC Elecs. Co. v. United States*, 816 F.2d 647, 657, 2 USPQ2d 1465, 1472 (Fed. Cir. 1987), *cert. denied*, 108 S.Ct. 748 (1988); *see also* 28 U.S.C. §2106 (1982) ("any . . . court of appellate jurisdiction . . . as may be just under the circumstances.").

To hold that a patentee has committed inequitable conduct, this court has uniformly held that *both* materiality and intent must be proven by clear and convincing evidence. *See, e.g., FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415, 5 USPQ2d 1112, 1115 (Fed. Cir. 1987). Thus, "[t]o be guilty of inequitable conduct, one must have intended to act inequitably." *Id.* Proof of deliberate scheming is unnecessary; gross negligence may constitute sufficient wrongful intent to support a holding of inequitable conduct. *See Reactive Metals & Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578, 1583-84, 226 USPQ 821, 825 (Fed. Cir. 1985).

[6] In the present case, however, there is no evidence of actual wrongful intent or gross negligence by the patentee. Helena's complete failure to present any evidence of intent likely follows its initial misunderstanding, which it later corrected, that "under the relevant case law, intent is not material to a determination of unenforceability, since Helena is *not* alleging fraud." As stated above, this court has uniformly held evidence of intent, not only material but, a *requirement* for a holding of inequitable conduct. Such evidence need not be direct, it may be inferred from the patentee's conduct. *See Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1538-39, 222 USPQ 553, 561-62 (Fed. Cir. 1984). Nevertheless, some evidence on the issue must exist.

Because Helena has failed to present any evidence, let alone clear and convincing evidence, that the '970 patent was procured by an applicant having withheld information through at least grossly negligent conduct, it has failed to raise a genuine issue for trial that the '970 patent is unenforceable.

E. *Helena's Other Defenses & Counterclaim*

[8] Because we have decided that Helena's accused product containing hemoglobin as the positive monitor catalyst literally infringes the '970 patent claims, we need not and do not review the district court's analysis of infringement under the doctrine of equivalents.

[9] We note the line of cases sometimes called "marking estoppel" cases, in which, under some circumstances, a party that marks its product with a patent number is estopped from asserting that the product is not covered by the patent. *See, e.g., Gridiron Steel Co. v. Jones & Laughlin Steel Corp.*, 361 F.2d 791, 796-97, 149 USPQ 877, 880-81 (6th Cir. 1966); *Collis Co. v. Consolidated Mach. Tool Corp.*, 41 F.2d 641, 645, 6 USPQ 109, 113 (8th Cir.), *cert. denied*, 282 U.S. 886 (1930); *Piaget Novelty Co. v. Headley*, 108 F. 870, 872 (2d Cir. 1901).

On appeal it is Helena's burden to show not only that the district court erred, but also to persuade this court that had such error not occurred the result might have been different. *See, e.g.*, 28 U.S.C. §2111 (1982); *Cable Elec. Prod., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1021, 226 USPQ 881, 884 (Fed. Cir. 1985) ("Even assuming that such errors were committed [by the district court], Cable must demonstrate that if the errors were corrected, the application of the law to the facts present would produce a different result. In short, such errors as may be demonstrated must have further been harmful.") (citations omitted); *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1345, 220 USPQ 777, 782 (Fed. Cir.) (in banc) (courts of appeal shall disregard harmless errors which do not affect parties' substantive rights), *cert. denied*, 469 U.S. 830 [225 USPQ 232] (1984). None of Helena's other charges of error rise to that level. The remaining "errors" concern matters on which the court made no specific rulings.

Although Helena charged SKD with unfair competition, *inter alia*, from interference with customer and vendor relationships and from patent misuse, the evidence on these matters is so inconsequential that the district court apparently did not treat it as a viable issue. Similarly, the assertion that the case should be dismissed for lack of jurisdiction based on an absence of direct evidence that Helena sold infringing products at the time SKD brought suit is meritless. Indirect evidence from which such inference may be drawn is adequate. Having reviewed the evidence called to our attention by Helena, we see no reason to remand for the district court to make specific rulings on these matters. No *prima facie* case was made out on any of them. Moreover, after the court issued its memorandum of findings of fact and conclusions of law without specific rulings, Helena failed to bring the alleged omissions to the trial court's attention. Helena's failure to give the court an opportunity to correct its alleged error in not ruling on these matters, under the circumstances here, could be deemed a waiver. Given their lack of substance, however, we are unpersuaded of prejudicial error in any event.

III
CONCLUSION

We affirm those portions of the district court's judgment holding claims 1, 2, 4, and 5 valid as between the parties, on different grounds. We also affirm that portion of the court's judgment finding that Helena's product containing lead acetate does not infringe the '970 patent. We reverse the portion of the court's judgment finding Helena's hemoglobin product noninfringing. We remand for calculation of damages.

COSTS

Each party shall bear its own costs of appeal.

MODIFIED IN PART, AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

District Court, S.D. New York

Berger & Gorin Inc. v. Gary Plastic Packaging Corp.

No. 84 Civ. 4164 (PNL)

Decided July 20, 1988

PATENTS

1. Patentability/Validity — Fraud or inequitable conduct (§115.15)

Title — Licenses (§150.05)

Patentee's taking of license in undisclosed technology does not, standing alone, require finding of deceitful intent, but rather such failure to disclose prior art must be considered based upon overall circumstances.

2. Patentability/Validity — Obviousness — Secondary considerations generally (§115.0907)

Plastic device for displaying belts that was designed at customer's request to serve industry need and that remained industry leader for years following its development is not obvious, nor is subsequent device used for hanging belts with stud buckles, in view of evidence demonstrating that belt marketing industry suffered for several years from problem which device was designed to remedy.

3. Infringement — Doctrine of equivalents — In general (§120.0701)

Plaintiff's patents for retail belt display are not infringed under doctrine of equivalents by defendant's display hanger for tongue-buckle belts which has tear-shaped fastening hole differing from plaintiff's horizontal slot and which allows easier use than plaintiff's fastening hole, or by defendant's display hanger for stud-buckle belts which has different double-flanged type hole to receive stud of buckle.

JUDICIAL PRACTICE AND PROCEDURE

4. Procedure — Defenses; laches; estoppel (§410.18)

REMEDIES

Monetary — Damages — Patents — Increased damages (§510.0507.07)

Defendant which acted in disregard for patentee's rights has committed willful infringement, even though it obtained opinion from counsel concerning patent's invalidity, since such casual opinion was retracted by attorney's subsequent, more thorough opinion that contained no suggestion of invalidity, and defendant's inequitable conduct as willful infringer deprives it of equitable defenses of laches and estoppel.

Particular patents — General and mechanical — Display belt hangers

3,710,996, Smilov and Kayen, improved belt hanger hook device for displaying tongue-buckle belts with price tag showing and with tail engaging means to prevent undetected removal of belt from hanger, valid and infringed.

4,063,669, Smilov and Kayen, belt hanger hook device for displaying belt and comprising tail loop for engaging with stud-buckle belts and for shielding buckles from accidental contact with other objects, valid and infringed.

Patent infringement action brought by Berger & Gorin Inc. against Gary Plastic Packaging Corp. Judgment of willful infringement by defendant by its 1975 and 1978 hangers.

James J. Daley and Albert Robin, New York, N.Y., for plaintiff.

Amster, Rothstein & Engelberg (Michael J. Berger, of counsel), New York, for defendant.

Leval, J.

This is an action for patent infringement. The two patents in question are for plastic belt hangers designed to display belts as merchandise in a store. Plaintiff Berger & Gorin, Inc. ("B&G") and defendant Gary Plastic Packaging Corp. ("Gary") both engage in the manufacture of plastic belt hangers.

Plaintiff's first patent No. 3,710,996 (the "'996" or "Snap-Tail" patent) was filed August 2, 1971 and issued January 16, 1973. It claims a belt-hanging device having a hook at the top (so as to hang the device from a merchandise display rod). (*See* Appendix I [omitted].) (On the hook portion are broad flat areas used to display size and brand names.) Hanging below the hook is a flexible strap (or tail) that bends at the middle (to engage the buckle of the belt). At the bottom of the tail is a mushroom-shaped projection and at the top is a hole slightly smaller than the head of the lower projection. After passing the tail through the buckle of the belt, the tail may be secured in the folded position by pushing the head of the projection at the bottom through the hole at the top. Halfway down the tail is a configuration of slits in the shape of an inverted T (whose bar is on the fold line of the tail). The prong of the belt buckle is secured to the hanger by rotating the hanger and pushing the tip of the prong into these slits.

The Snap-Tail hanger represented improvement in several respects over prior art. Earlier hangers were often made with a short tab, which had a similar hook at the top but which did not fold. The tab had a single hold or inverse T-slit, which was used to attach the belt buckle (TE 24, 25.) The tab would be inserted into the belt buckle, whose prong would be pushed through the hole in the tab. Such devices were unreliably secured to the belt; the hangers easily became detached from the belt. Also the belt would hang at an angle which gave an unpleasing appearance and took extra space, diminishing the number of belts that could be displayed on the rod.

The '996 Snap-Tail hanger improved these features. It was far more securely attached to the belt. In addition, the hanger and belt hung straight down in the same plane, perpendicular to the merchandise rod.

The second B&G patent (filed September 10, 1975, issued December 20, 1979) under No. 4,063,669 (the "'669" or "Stud-Belt patent) is identical to the Snap-Tail but with an additional feature designed for use with stud belts. (*See* Appendix II. [omitted])

A stud belt is designed differently and functions differently from a conventional prong-buckle belt. Prong-buckle belts are worn by passing the free end through the open portion of the buckle and inserting the prong into a hole in the belt. Stud-belt buckles, in contrast, do not have an opening or a pivoting prong. The buckle is generally solid and lays over the free end of the belt. On the underside of the buckle is a laterally protruding stud which is inserted into a hole in the other end of the belt. Sometimes such studs

elements of Stuart Hall's planner pages may be primarily nonfunctional under the standard explained in *Aromatique*, even if such elements as lines on which to write appointments throughout the day are not.

D. *Likelihood of Confusion*

The district court characterized the survey commissioned by Stuart Hall regarding the likelihood of confusion between its product and Ampad's as "misleading," and accorded it no weight regarding inherent distinctiveness or likelihood of confusion.[4] As we state *supra*, the survey is not relevant to the issue of inherent distinctiveness.

In *Mutual of Omaha Insurance Co. v. Novak*, this court held that surveys are an appropriate form in which to produce evidence of actual confusion. 836 F.2d 397, 400 [5 USPQ2d 1314] (8th Cir. 1987), *cert. denied*, 488 U.S. 933 (1988). The court went on to say that "[b]ecause manifestations of actual confusion serve as strong evidence of a likelihood of confusion, and may, in fact, be the best such evidence, this survey should be given substantial weight unless seriously flawed." *Id.* at 400 (internal citations omitted); *see also Woodsmith Pub. Co. v. Meredith Corp.*, 904 F.2d 1244, 1249 [15 USPQ2d 1053] (8th Cir. 1990) (stating that, although not required to show likelihood of confusion, surveys are probably the most accurate evidence of actual confusion).

The district court's complaints about the survey are not particularly significant, nor do they necessarily address actual flaws in the survey as performed. The court stated that it would have preferred a survey designed to enforce only casual and limited attention to the products and a time-delayed resurvey. The more limited and casual the attention to the products, however, the more likely consumers are to indicate confusion between them. The court verified this hypothesis itself when it also complained that some people surveyed may have been so casual that elements not at issue in the case may have been enough to cause an inference of identical source. The court is splitting hairs here: it would prefer a survey of people who are casual, but not *too* casual. The court also expressed concern that some people surveyed may have skewed their answers due to their views on political economy, but the testimony of John Bunge, Stuart Hall's survey expert, indicated that not only were the people surveyed not told that the survey concerned issues of trade dress protection and thus potentially market competition, the interviewers and their employers were also not told for the specific purpose of avoiding such bias.

[3] No evidence was presented to indicate that the survey was flawed. Stuart Hall's expert testified that he had performed approximately 200 trademark-related consumer surveys with his current company, and had performed over 1,000 consumer surveys throughout his marketing career. His testimony indicates strict adherence to and extensive knowledge of standard methodology for trademark-related consumer surveys, and attention to the requirements of trademark law when designing surveys in general and this survey in particular. The testimony of Ampad's expert is, as the district court itself points out, unimpressive, and does nothing to indicate the presence of real flaws in the survey.

On remand, the district court must reconsider the evidence provided by the survey on the likelihood of confusion between Stuart Hall and Ampad products if it finds that Stuart Hall has shown that its trade dress is inherently distinctive or has secondary meaning and that it is primarily nonfunctional.

III. CONCLUSION

We reverse the district court's denial of Stuart Hall's motion for a preliminary injunction because the court erred in applying a novel and unrecognized test for inherent distinctiveness, failed to consider the factors that can properly support a finding of secondary meaning, failed to make a complete finding on nonfunctionality, and accorded no weight to Stuart Hall's survey on likelihood of confusion. We remand the case to the district court for reconsideration of Stuart Hall's motion for preliminary relief analyzing Stuart Hall's likelihood of success on the merits in accordance with the law as outlined in this opinion.

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[4] It is not clear from the district court's memorandum and order whether it made any finding on the likelihood of confusion element. We presume, given the court's treatment of the survey, that if there was a finding, it was that there was no likelihood of confusion.

U.S. Court of Appeals
Federal Circuit

In re Brana

No. 93-1393

Decided March 30, 1995

PATENTS

1. Patentability/Validity — Utility (§115.10)

Patentability/Validity — Specification — Enablement (§115.1105)

Application for pharmaceutical invention did not fail to disclose specific disease against which claimed compounds are useful, and thereby fail to satisfy enablement requirement of 35 USC 112, since specification, which favorably compares compounds of invention with known compounds found to be highly effective against lymphocytic leukemia tumor models, implicitly asserts that claimed compounds are also highly effective against those models, and since tumor models are cell lines representing specific lymphocytic tumors.

2. Patentability/Validity — Utility (§115.10)

Patentability/Validity — Specification — Enablement (§115.1105)

Patent and Trademark Office improperly rejected, for lack of utility, application claims for pharmaceutical compounds used in cancer treatment in humans, since neither nature of invention nor evidence proferred by PTO would cause one of ordinary skill in art to reasonably doubt asserted utility, and since even if utility of compounds could be reasonably questioned, evidence that compounds within scope of claims, and other structurally similar compounds, are effective as chemotherapeutic agents in animals would be sufficient to convince one skilled in art of asserted utility; absence of evidence that claimed compounds have chemotherapeutic effect in humans does not warrant contrary conclusion, since proof of alleged pharmaceutical property for compound by statistically significant tests using standard experimental animals is sufficient to establish utility.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Miguel F. Brana, Jose M.C. Berlanga, Marina M. Moset, Erich Schlick and Gerhard Keilhauer, serial no. 07/533,944, filed June 4, 1990, which is a continuation of serial no. 213,690, filed June 30, 1988. From decision upholding examiner's rejection of claims 10-13, applicants appeal. Reversed.

Malcolm J. MacDonald, Herbert B. Keil, and David S. Nagy, Washington, D.C., for appellants.

Fred E. McKelvey, Solicitor, PTO; Albin F. Drost, Deputy Solicitor; Richard E. Schafer, Teddy S. Gron, Joseph G. Piccolo and Richard L. Torczon, Associate Solicitors, for appellee.

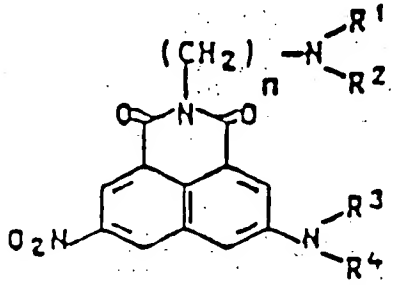
Before Plager, Lourie, and Rader, circuit judges.

Plager, J.

Miguel F. Brana, *et al.* (applicants), appeal the March 19, 1993 decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), in Appeal No. 92-1196. The Board affirmed the examiner's rejection of claims 10-13 of patent application Serial No. 533,944 under 35 U.S.C. § 112 ¶1 (1988).[1] The examiner's rejection, upon which the Board relied in rendering its decision, was based specifically on a challenge to the utility of the claimed compounds and the amount of experimentation necessary to use the compounds. We conclude the Board erred, and reverse.

I. BACKGROUND

On June 30, 1988, applicants filed patent application Serial No. 213,690 (the '690 application)[2] directed to 5-nitrobenzo-[de]isoquinoline-1,3-dione compounds, for use as antitumor substances, having the following formula:



where n is 1 or 2, R^1 and R^2 are identical or different and are each hydrogen, C1-C6–

[1] Unless otherwise noted, all United States Code citations are to the 1988 edition.

[2] This is a divisional of patent application Serial No. 110,871 filed October 21, 1987.

alkyl, C1-C6-hydroxyalkyl, pyrrolidinyl, morpholino, piperidinyl or piperacinyl, and R^3 and R^4 are identical or different and are each hydrogen, C1-C6-alkyl, C1-C6-acyl, C2-C7-alkoxycarbonyl, ureyl, aminocarbonyl or C2-C7-alkylaminocarbonyl. These claimed compounds differ from several prior art benzo[de]isoquinoline-1,3-dione compounds due to the presence of a nitro group (O2N) at the 5-position and an amino or other amino group (NR^3R^4) at the 8-position of the isoquinoline ring.

The specification states that these nonsymmetrical substitutions at the 5- and 8-positions produce compounds with "a better action and a better action spectrum as antitumor substances" than known benzo[de]isoquinolines, namely those in K.D. Paull et al., *Computer Assisted Structure–Activity Correlations, Drug Research, 34(II)*, 1243-46 (1984) (Paull). Paull describes a computer-assisted evaluation of benzo[de]isoquinoline-1,3-diones and related compounds which have been screened for antitumor activity by testing their efficacy *in vivo*[3] against two specific implanted murine (i.e., utilizing mice as test subjects) lymphocytic leukemias, P388 and L1210.[4] These two *in vivo* tests are widely used by the National Cancer Institute (NCI) to measure the antitumor properties of a compound. Paull noted that one compound in particular, benzo[de]isoquinoline-1,3(2H)dione,5--amino-2(2-dimethyl-aminoethyl [sic]) (hereinafter "NSC 308847"), was found to show excellent activity against these two specific tumor models. Based on their analysis, compound NSC 308847 was selected for further studies by NCI. In addition to comparing the effectiveness of the claimed compounds with structurally similar compounds in Paull, applicants' patent specification illustrates the cytotoxicity of the claimed compounds against human tumor cells, *in vitro*,[5] and concludes that these tests "had a good action."[6]

The examiner initially rejected applicants' claims in the '690 application as obvious under 35 U.S.C. § 103 in light of U.S. Patent No. 4,614,820, issued to and referred to hereafter as Zee-Cheng *et al.* Zee-Cheng *et al.* discloses a benzo[de]isoquinoline compound for use as an antitumor agent with symmetrical substitutions on the 5-position and 8-position of the quinoline ring; in both positions the substitution was either an amino or nitro group.[7] Although not identical to the applicants' claimed compounds, the examiner noted the similar substitution pattern (i.e., at the same positions on the isoquinoline ring) and concluded that a mixed substitution of the invention therefore would have been obvious in view of Zee-Cheng *et al.*

In a response dated July 14, 1989, the applicants rebutted the § 103 rejection. Applicants asserted that their mixed disubstituted compounds had unexpectedly better antitumor properties than the symmetrically substituted compounds in Zee–Cheng *et al.* In support of this assertion applicants attached the declaration of Dr. Gerhard Keilhauer. In his declaration Dr. Keilhauer reported that his tests indicated that applicants' claimed compounds were far more effective as antitumor agents than the compounds disclosed in Zee-Cheng *et al.* when tested, *in vitro*, against two specific types of human tumor cells, HEp and HCT-29.[8] Applicants further noted that, although the differences between the compounds in Zee-Cheng *et al.* and applicants' claimed compounds were slight, there was no suggestion in the art that these improved results (over Zee-Cheng *et al.*) would have been expected. Although the applicants overcame the § 103 rejection, the examiner nevertheless issued a final rejection, on different grounds, on September 5, 1989.

[3] *In vivo* means "[i]n the living body, referring to a process occurring therein." *Steadman's Medical Dictionary* 798 (25th ed. 1990). *In vitro* means "[i]n an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture media." *Id.*

[4] The analysis in Paull consisted of grouping the previously-tested compounds into groups based on common structural features and cross-referencing the various groups, in light of the success rates of the group as a whole, to determine specific compounds that may be effective in treating tumors.

[5] *See supra* note 3.

[6] The specification does not state the specific type of human tumor cells used in this test.

[7] The chemical compound in Zee-Cheng *et al.* is labeled a 3,6-disubstituted-1,8-naphthalimide and uses different numbering for the positions on the isoquinoline ring. The structure of this compound, however, is identical to that claimed by the applicants except for symmetrical substitutions at the 5-position and the 8-position of the isoquinoline ring. Zee-Cheng *et al.* teaches identical substitutions of amino or nitro groups while applicants claim a nitro group substitution at the 5-position and an amino group substitution at the 8-position.

[8] HEp cells are derived from laryngeal cancer and HCT-29 cells from colon cancer.

On June 4, 1990, applicants filed a continuation application, Serial No. 533,944 (the '944 application), from the above-mentioned '690 application. Claims 10-13, the only claims remaining in the continuation application, were rejected in a final office action dated May 1, 1991. Applicants appealed the examiner's final rejection to the Board.

In his answer to the applicants' appeal brief, the examiner stated that the final rejection was based on 35 U.S.C. § 112 ¶1.[9] The examiner first noted that the specification failed to describe any specific disease against which the claimed compounds were active. Furthermore, the examiner concluded that the prior art tests performed in Paull and the tests disclosed in the specification were not sufficient to establish a reasonable expectation that the claimed compounds had a practical utility (i.e. antitumor activity in humans).[10]

In a decision dated March 19, 1993, the Board affirmed the examiner's final rejection. The three-page opinion, which lacked any additional analysis, relied entirely on the examiner's reasoning. Although noting that it also would have been proper for the examiner to reject the claims under 35 U.S.C. § 101, the Board affirmed solely on the basis of the Examiner's § 112 ¶1 rejection. This appeal followed.

II. DISCUSSION

At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant prove regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.[11] We note the Commissioner has recently addressed this question in his Examiner Guidelines for Biotech Applications, *see* 60 Fed. Reg. 97 (1995); 49 Pat. Trademark & Copyright J. (BNA) No. 1210, at 234 (Jan. 5, 1995).

The requirement that an invention have utility is found in 35 U.S.C. § 101: "Whoever invents . . . any new and *useful* . . . composition of matter . . . may obtain a patent therefor. . . ." (emphasis added). It is also implicit in § 112 ¶1, which reads:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it.

As noted, although the examiner and the Board both mentioned § 101, and the rejection appears to be based on the issue of whether the compounds had a practical utility, a § 101 issue, the rejection according to the Board stands on the requirements of § 112 ¶1. It is to that provision that we address ourselves.[12] The Board gives two reasons for the rejection;[13] we will consider these in turn.

1.

The first basis for the Board's decision was that the applicants' specification failed to disclose a specific disease against which the

[9] The examiner's answer noted that the final rejection also could have been made under 35 U.S.C. § 101 for failure to disclose a practical utility.

[10] The examiner subsequently filed two supplemental answers in response to arguments raised by the applicants in supplemental reply briefs.

[11] *See, e.g., Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *In re Bergel*, 292 F.2d 958, 130 USPQ 205 (CCPA 1961).

[12] This court's predecessor has determined that absence of utility can be the basis of a rejection under both 35 U.S.C. § 101 and § 112 ¶1. *In re Jolles*, 628 F.2d 1322, 1326 n.11, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) ("[I]f such compositions are in fact useless, appellant's specification cannot have taught how to use them."). Since the Board affirmed the examiner's rejection based solely on § 112 ¶1, however, our review is limited only to whether the application complies with § 112 ¶1.

[13] The Board's decision did not expressly make any independent factual determinations or legal conclusions. Rather, the Board stated that it "agree[d] with the examiner's well reasoned, well stated and fully supported by citation of relevant precedent position in every particular, and any further comment which we might add would be redundant." *Ex parte Brana et al.*, No. 92-1196 (Bd. Pat. App. & Int. March 19, 1993) at 2-3. Therefore, reference in this opinion to Board findings are actually arguments made by the examiner which have been expressly adopted by the Board.

claimed compounds are useful, and therefore, absent undue experimentation, one of ordinary skill in the art was precluded from using the invention. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). In support, the Commissioner argues that the disclosed uses in the '944 application, namely the "treatment of diseases" and "antitumor substances," are similar to the nebulous disclosure found insufficient in *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). This argument is not without merit.

In *Kirk* applicants claimed a new class of steroid compounds. One of the alleged utilities disclosed in the specification was that these compounds possessed "high biological activity." *Id.* at 938, 153 USPQ at 50. The specification, however, failed to disclose which biological properties made the compounds useful. Moreover, the court found that known specific uses of similar compounds did not cure this defect since there was no disclosure in the specification that the properties of the claimed compounds were the same as those of the known similar compounds. *Id.* at 942, 153 USPQ at 53. Furthermore, it was not alleged that one of skill in the art would have known of any specific uses, and therefore, the court concluded this alleged use was too obscure to enable one of skill in the art to use the claimed invention. *See also Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973).

[1] *Kirk* would potentially be dispositive of this case were the above-mentioned language the only assertion of utility found in the '944 application. Applicants' specification, however, also states that the claimed compounds have "a better action and a better action spectrum as antitumor substances" than known compounds, specifically those analyzed in Paull. As previously noted, *see supra* note 4, Paull grouped various benzo[de]isoquinoline-1,3-diones, which had previously been tested *in vivo* for antitumor activity against two lymphocytic leukemia tumor models (P388 and L1210), into various structural classifications and analyzed the test results of the groups (i.e. what percent of the compounds in the particular group showed success against the tumor models). Since one of the tested compounds, NSC 308847, was found to be highly effective against these two lymphocytic leukemia tumor models,[14] applicants' favorable comparison implicitly asserts that their claimed compounds are highly effective (i.e. useful) against lymphocytic leukemia. An alleged use against this particular type of cancer is much more specific than the vaguely intimated uses rejected by the courts in *Kirk* and *Kawai*. *See, e.g., Cross v. Iizuka*, 753 F.2d at 1048, 224 USPQ at 745 (finding the disclosed practical utility for the claimed compounds — the inhibition of thromboxane synthetase in human or bovine platelet microsomes — sufficiently specific to satisfy the threshold requirement in *Kirk* and *Kawai*.)

The Commissioner contends, however, that P388 and L1210 are not diseases since the only way an animal can get sick from P388 is by a direct injection of the cell line. The Commissioner therefore concludes that applicants' reference to Paull in their specification does not provide a specific disease against which the claimed compounds can be used. We disagree.

As applicants point out, the P388 and L1210 cell lines, though technically labeled tumor models, were originally derived from lymphocytic leukemias in mice. Therefore, the P388 and L1210 cell lines do represent actual specific lymphocytic tumors; these models will produce this particular disease once implanted in mice. If applicants were required to wait until an animal naturally developed this specific tumor before testing the effectiveness of a compound against the tumor *in vivo*, as would be implied from the Commissioner's argument, there would be no effective way to test compounds *in vivo* on a large scale.

We conclude that these tumor models represent a specific disease against which the claimed compounds are alleged to be effective. Accordingly, in light of the explicit reference to Paull, applicants' specification alleges a sufficiently specific use.

2.

The second basis for the Board's rejection was that, even if the specification did allege a specific use, applicants failed to prove that the claimed compounds are useful. Citing various references,[15] the Board found, and the Commissioner now argues, that the tests offered by the applicants to prove utility were inadequate to convince one of ordinary skill in the art that the claimed compounds are useful as antitumor agents.[16]

This court's predecessor has stated:

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). From this it follows that the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. *Id.* at 224, 169 USPQ at 370. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. *See In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)."

[2] The PTO has not met this initial burden. The references cited by the Board, Pazdur and Martin,[18] do not question the usefulness of any compound as an antitumor agent or provide any other evidence to cause one of skill in the art to question the asserted utility of applicants' compounds. Rather, these references merely discuss the therapeutic predictive value of *in vivo* murine tests — relevant only if applicants must prove the ultimate value in humans of their asserted utility. Likewise, we do not find that the nature of applicants' invention alone would cause one of skill in the art to reasonably doubt the asserted usefulness.

The purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles. *In re Jolles*, 628 F.2d at 1327, 206 USPQ at 890. Modern science has previously identified numerous successful chemotherapeutic agents. In addition, the prior art, specifically Zee Cheng *et al.*, discloses structurally similar compounds to those claimed by the applicants which have been proven *in vivo* to be effective as chemotherapeutic agents against various tumor models.

Taking these facts — the nature of the invention and the PTO's proffered evidence — into consideration we conclude that one skilled in the art would be without basis to reasonably doubt applicants' asserted utility on its face. The PTO thus has not satisfied its initial burden. Accordingly, applicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of § 112. *See In re Marzocchi*, 439 F.2d at 224, 169 USPQ at 370.

We do not rest our decision there, however. Even if one skilled in the art would have reasonably questioned the asserted utility, i.e., even if the PTO met its initial burden thereby shifting the burden to the applicants to offer rebuttal evidence, applicants proffered sufficient evidence to convince one of skill in the art of the asserted utility. In particular, applicants provided through Dr. Kluge's declaration [19] test results showing that several compounds within the scope of the claims exhibited significant antitumor activity against the L1210 standard tumor

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[14] Paull also found NSC 308847 to be effective against two other test models, B16 melanoma and Colon C872.

[15] *See* Pazdur et al., *Correlation of Murine Antitumor Models in Predicting Clinical Drug Activity in Non-Small Cell Lung Cancer: A Six Year Experience*, 3 *Proceedings Am. Soc. Clin. Oncology* 219 (1984); Martin et al., *Role of Murine Tumor Models in Cancer Research*, 46 *Cancer Research* 2189 (April 1986).

[16] As noted, this would appear to be a §101 issue, rather than §112.

[17] *See also In re Novak*, 306 F.2d 924, 928, 134 USPQ 335, 337 (CCPA 1962) (stating that it is proper for the examiner to request evidence to substantiate an asserted utility unless one with ordinary skill in the art would accept the allegations as obviously valid and correct); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956) ("[W]here the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry ... no further evidence is required."). *But see In re Marzocchi*, 439 F.2d at 223, 169 USPQ at 369-70 ("In the field of chemistry generally there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles.").

[18] *See supra* note 15.

[19] The declaration of Michael Kluge was signed and dated June 19, 1991. This declaration listed test results (i.e. antitumor activity) of the claimed compounds, *in vivo*, against L1210 tumor cells and concluded that these compounds would likely be clinically useful as anti-cancer agents. Enablement, or utility, is determined as of the application filing date. *In re Glass*, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974). The Kluge declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. *In re Marzocchi*, 439 F.2d at 224 n.4, 169 USPQ at 370 n.4. It does not render an insufficient disclosure enabling, but instead goes to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility).

model *in vivo*. Such evidence alone should have been sufficient to satisfy applicants' burden.

The prior art further supports the conclusion that one skilled in the art would be convinced of the applicants' asserted utility. As previously mentioned, prior art — Zee Cheng *et al.* and Paull — disclosed structurally similar compounds which were proven *in vivo* against various tumor models to be effective as chemotherapeutic agents. Although it is true that minor changes in chemical compounds can radically alter their effects on the human body, *Kawai*, 480 F.2d at 891, 178 USPQ at 167, evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility. *See Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974); *Kawai*, 480 F.2d 880, 178 USPQ 158.

The Commissioner counters that such *in vivo* tests in animals are only preclinical tests to determine whether a compound is suitable for processing in the second stage of testing, by which he apparently means *in vivo* testing in humans, and therefore are not reasonably predictive of the success of the claimed compounds for treating cancer in humans.[20] The Commissioner, as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. *See Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Our court's predecessor has determined that proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility. *In re Krimmel*, 292 F.2d 948, 953, 130 USPQ 215, 219 (CCPA 1961); *see also In re Bergel*, 292 F.2d 958, 130 USPQ 205 (CCPA 1961). In concluding that similar *in vivo* tests were adequate proof of utility the court in *In re Krimmel* stated:

> We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.

Krimmel, 292 F.2d at 953, 130 USPQ at 219. Moreover, NCI apparently believes these tests are statistically significant because it has explicitly recognized both the P388 and L1210 murine tumor models as standard screening tests for determining whether new compounds may be useful as antitumor agents.

In the context of this case the Martin and Pazdur references, on which the Commissioner relies, do not convince us otherwise. Pazdur only questions the reliability of the screening tests against lung cancer; it says nothing regarding other types of tumors. Although the Martin reference does note that some laboratory oncologists are skeptical about the predictive value of *in vivo* murine tumor models for human therapy, Martin recognizes that these tumor models continue to contribute to an increasing human cure rate. In fact, the authors conclude that this perception (i.e. lack of predictive reliability) is not tenable in light of present information.

On the basis of animal studies, and controlled testing in a limited number of humans (referred to as Phase I testing), the Food and Drug Administration may authorize Phase II clinical studies. *See* 21 U.S.C. § 355(i)(1); 5 C.F.R. § 312.23 (a)(5), (a)(8) (1994). Authorization for a Phase II study means that the drug may be administered to a larger number of humans, but still under strictly supervised conditions. The purpose of the Phase II study is to determine primarily the safety of the drug when administered to a larger human population, as well as its potential efficacy under different dosage regimes. *See* 21 C.F.R. § 312.21(b).

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. *Scott*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

In view of all the foregoing, we conclude that applicants' disclosure complies with the requirements of 35 U.S.C. § 112 ¶1.

3.

The Commissioner takes this opportunity to raise the question of this court's standard of review when deciding cases on appeal from the PTO. Traditionally we have recited our standard of review to be, with regard to questions of law, that review is without deference to the views of the Agency, *In re Donaldson*, 16 F.3d 1189, 1192, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994) (in banc), *In re Caveney*, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed. Cir. 1985), and with regard to questions of fact, we defer to the Agency unless its findings are "clearly erroneous." *See, e.g., In re Baxter Travenol Labs*, 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re De Blauwe*, 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984).

With regard to judgment calls, those questions that fall "[s]omewhere near the middle of the fact-law spectrum," this court has recognized "the falseness of the fact-law dichotomy, since the determination at issue, involving as it does the application of a general legal standard to particular facts, is probably most realistically described as neither of fact nor law, but mixed." *Campbell v. Merit Systems Protection Board*, 27 F.3d 1560, 1565 (Fed. Cir. 1994). When these questions of judgment are before us, whether we defer, and the extent to which we defer, turns on the nature of the case and the nature of the judgment. *Id.* ("Characterization therefore must follow from an *a priori* decision as to whether deferring ... is sound judicial policy. We would be less than candid to suggest otherwise.").

The Commissioner contends that the appropriate standard of review for this court regarding questions of law, of fact, and mixed questions of law and fact, coming to us from the PTO is found in the Administrative Procedure Act (APA) at 5 U.S.C. § 706. The standard set out there is that "[t]he reviewing court shall ... hold unlawful and set aside agency action, findings, and conclusions found to be — (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; ... (E) unsupported by substantial evidence ..." The Commissioner is of the view that the stated standard we now use, which is the traditional standard of review for matters coming from a trial court, is not appropriate for decisions coming from an agency with presumed expertise in the subject area, and is not in accord with law.[21]

Applicants argue that by custom and tradition, recognized by the law of this court, the standard of review we have applied, even though inconsistent with the standard set forth in the APA, nevertheless is a permissible standard. In our consideration of this issue, there is a reality check: would it matter to the outcome in a given case which formulation of the standard a court articulates in arriving at its decision? The answer no doubt must be that, even though in some cases it might not matter, in others it would, otherwise the lengthy debates about the meaning of these formulations and the circumstances in which they apply would be unnecessary.

A preliminary question, then, is whether this is one of those cases in which a difference in the standard of review would make a difference in the outcome. The ultimate issue is whether the Board correctly applied the § 112 ¶1 enablement mandate and its implicit requirement of practical utility, or perhaps more accurately the underlying requirement of § 101, to the facts of this case. As we have explained, the issue breaks down into two subsidiary issues: (1) whether a person of ordinary skill in the art would conclude that the applicants had sufficiently described particular diseases addressed by the invention, and (2) whether the Patent Act supports a requirement that makes human testing a prerequisite to patentability under the circumstances of this case.

The first subsidiary issue, whether the application adequately described particular diseases, calls for a judgment about what the various representations and discussions contained in the patent application's specification would say to a person of ordinary skill in

[20] We note that this discussion is relevant to the earlier discussion as well. If we were to conclude that these *in vivo* tests are insufficient to establish usefulness for the claimed compounds, that would bear on the issue of whether one skilled in the art would, in light of the structurally similar compounds in Paull and Zee Cheng *et al.*, have cause to doubt applicants' asserted usefulness for the compounds.

[21] Congress enacted the Administrative Procedure Act (APA) on June 11, 1946. *See* 1 *Kenneth Culp Davis, Administrative Law Treatise*, § 1:7 (2d ed. 1978). The APA sets forth a framework for administrative agency procedure and provides judicial review for persons adversely affected by final agency actions. Chapter 7, codified at 5 U.S.C. §§ 701-706, contains the APA judicial review provisions, including the standard of review provision quoted above.

the art. We have considered that question carefully, and, for the reasons we explained above in some detail, we conclude that the Board's judgment on this question was erroneous. Our conclusion rests on our understanding of what a person skilled in the art would gather from the various art cited, and from the statements in the application itself. We consider the Board's error to be sufficiently clear that it is reversible whether viewed as clear error or as resulting in an arbitrary and capricious decision.

The second subsidiary issue, whether human testing is a prerequisite to patentability, is a pure question of law: what does the practical utility requirement mean in a case of this kind. Under either our traditional standard or under the APA standard no deference is owed the Agency on a question of law, and none was accorded.

If the question concerning the standard of review; raised by the Commissioner, is to be addressed meaningfully, it must arise in a case in which the decision will turn on that question, and, recognizing this, the parties fully brief the issue. This is not that case. We conclude that it is not necessary to the disposition of this case to address the question raised by the Commissioner; accordingly, we decline the invitation to do so.

III. CONCLUSION

The Board erred in affirming the examiner's rejection under 35 U.S.C. § 112 ¶1. The decision is reversed.

REVERSED.

U.S. Court of Appeals
Federal Circuit

Ortho Pharmaceutical Corp. v. Genetics Institute Inc.

No. 93-1166

Decided April 5, 1995

PATENTS

1. Title — Construction of license agreement (§150.07)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Parties; standing (§410.07)

Licensee of patent for product used in production of erythropoietin lacks standing to bring independent action against defendant whom patentee has already sued for same acts of alleged infringement, since licensee's rights in patent under license are non-exclusive, and since licensee's right to sell unpatented EPO abroad is not proprietary right arising from patent and thus does not confer standing; clause in licensing agreement granting licensee right to bring infringement action if licensor fails to sue within reasonable period does not confer co-plaintiff standing on licensee, since contract clause cannot overcome requirement that suit be brought by party having proprietary interest in patent, and since, under circumstances presented, licensee has effectively consented to suit in name of patentee alone.

Particular patents — Chemical — erythropoietin

4,703,008, Fu-Kuen Lin, DNA sequences encoding erythropoietin, dismissal of infringement action for lack of standing affirmed.

Appeal from the U.S. District Court for the District of Massachusetts, Young, J.; 27 USPQ2d 1578.

Action by Amgen Inc. against Chugai Pharmaceutical Co. Ltd. and Genetics Institute Inc., for patent infringement, consolidated with patent infringement action filed by Ortho Pharmaceutical Corp., Cilag Gesellschaft M.B.H., Cilag N.V., Cilag Ltd., Cilag S.A.R.L., Cilag G.M.B.H., Cilag S.P.A., Cilag-Medicamenta LDA., Johnson & Johnson S.A. (Cilag Division), Cilag AB, Cilag AG and Cilag AG International, against Genetics Institute Inc. and Amgen Inc. From dismissal of its action for lack of standing, Ortho Pharmaceutical Corp. appeals. Affirmed.

Eugene M. Gelernter and David F. Dobbins, of Patterson, Belknap, Webb & Tyler, New York, N.Y., for plaintiff-appellant.

William F. Lee, William G. McElwain, and David B. Bassett, of Hale & Dorr, Boston, Mass.; John O. Nelson and D. Dennis Allegretti, of Allegretti & Witcoff, Boston; Steven M. Odre and Stuart L. Watt, Thousand Oaks, Calif., for defendants-appellees.

Before Archer, chief judge, and Nies * and Michel, circuit judges.

Nies, J.

This appeal raises a question of a patent licensee's standing to sue an infringer in the name of the patentee/licensor. Ortho Pharmaceutical Corporation is a licensee of Amgen, Inc., owner of United States Patent No. 4,703,008 (the '008 patent). Ortho and its sublicensees filed suit against Genetics Institute for infringement of the '008 patent in the District Court for the District of Massachusetts. The district court dismissed Ortho's suit concluding that Ortho was a nonexclusive licensee and, therefore, lacked standing. *Ortho Pharmaceutical Corp. v. Genetics Institute, Inc.*, Civil Action 91-12174-Y (D. Mass. Dec. 4, 1992) (judgment) (reported *sub nom. Amgen, Inc. v. Chugai Pharmaceutical Co.*, 808 F. Supp. 894, 27 USPQ2d 1578). We affirm.

I.

The '008 patent claims a product used for the production of erythropoietin (EPO), a hormone that stimulates the synthesis of red blood cells in bone marrow. The '008 patent claims a purified and isolated DNA sequence encoding human EPO and host cells transformed or transfected with a DNA sequence in a manner allowing host cells to express EPO. The claims do not claim the EPO product itself.[1]

In 1984, three years prior to the issuance of the patent, Amgen and Kirin Brewery Company established a joint venture, Kirin-Amgen, Inc. At that time, Amgen, as owner of the then-pending application for the '008 patent, assigned certain rights to Kirin-Amgen. In 1985, Ortho entered into Product License Agreements (PLAs)[2] with Kirin-Amgen and Amgen separately under which Ortho was allowed limited rights to manufacture in the United States and sell EPO in the United States and in certain foreign countries in which the licensors were seeking to obtain patents on various products and processes, including EPO itself.

On October 27, 1987, the date the '008 patent issued, Kirin-Amgen assigned the patent to Amgen. On the same date, Amgen brought suit for infringement against Genetics and Chugai. The trial of Amgen's suit was bifurcated into liability and damages phases. Shortly before trial on liability, Ortho attempted to intervene under Fed. R. Civ. P. 24, either as a matter of right or permissively, based on its rights under the license from Amgen. This motion was denied on the grounds of untimeliness and because Ortho's interests were adequately represented by Amgen respecting liability, a decision Ortho did not appeal. Following a bench trial on liability, claims 2, 4, and 6 of the '008 patent were held not to be invalid or unenforceable and found to be infringed by both Chugai and Genetics Institute. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 13 USPQ2d 1737 (D. Mass. 1989). This court affirmed that judgment on interlocutory appeal. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d at 1200, 18 USPQ2d at 1016.

Ortho and its European sublicensees then filed a suit against Genetics Institute in the same court. Before an answer was filed, they amended the complaint to name Amgen as a defendant and subsequently moved to realign Amgen as an involuntary plaintiff. Genetics and Amgen filed motions to dismiss or for summary judgment on the ground of the plaintiff's lack of standing or for failure to state a claim. Ortho and the co-plaintiffs cross-moved to intervene in the Amgen litigation for the purpose of securing part of the damages. Ortho's suit was consolidated with the Amgen suit.

In reply to the defendants' motions, Ortho again asserted its rights as a licensee of Amgen. In particular, Ortho relied on Paragraph 2.01 of the PLA license, which provides:

> (a) AMGEN hereby grants to ORTHO but not AFFILIATES, except as hereinafter provided, an exclusive license to make in one location, have made and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENSED TERRITORY.
> (b) AMGEN, having received the consent of Kirin Brewery Co., Ltd., hereby grants to ORTHO but not AFFILIATES, an exclusive license, except as against AMGEN's rights under this AGREEMENT in the LICENSED TERRITORY, to make EPO in one location in the United States for use and sale outside the LI-

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* Circuit Judge Nies vacated the position of Chief Judge on March 17, 1994.

[1] For a full analysis of the invention, see *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

[2] In 1988, the PLAs replaced the Technological License Agreements, entered at the same time as the PLAs, upon approval in France of recombinant EPO for human use.

149 (CCPA, 1944); and Vanity Fair Mills, Inc. v. Pedigree Fabrics, Inc., 73 USPQ 438 (CCPA, 1947).

It is opposer's contention that applicant has adopted opposer's "INDIA" mark in its entirety, and has added thereto only descriptive wording and background design, which is no aid in distinguishing applicant's goods from opposer's goods. Further it is contended by opposer that applicant's mark must be characterized as an "INDIA" mark, or at the very most as "AN INDIA VILLAGE". Opposer submits that in either case, confusion is likely.

Applicant takes the position that in appearance and in sound the marks are so different that likelihood of confusion is nonexistent. Applicant submits that the word "India" is generic and geographical. It is argued on this basis that albeit its mark includes "INDIA", this point of similarity however cannot be determinative of the issue of likelihood of confusion.

[2] The word "INDIA" is geographical. As a general rule, trademarks involving a geographical term are "weak" and are entitled to a narrow scope of protection. See: American Liberty Insurance Company v. American Liberty Life Insurance Company, 136 USPQ 248 (DC Ga., 1962); General Motors Corporation v. Cadillac Marine & Boat Co. et al., 140 USPQ 447 (DC Mich., 1964); In re Blue Lake Producers Cooperative, 92 USPQ 334 (CCPA, 1952). This is particularly true here where the geographical significance of "INDIA" in applicant's mark is apparent and would indicate an association with that country rather than with opposer.

It is true that "AN INDIA VILLAGE" is not gramatically correct but there is an inherent ambiguity in the word "Indian" for said word can relate to matters or things pertaining to Western Hemisphere Indians or matters or things pertaining to the Republic of India. Thus the term india ink and india gum are considered correct notwithstanding the grammatical deficiency. A reference to "India Village" would connote geographical origin in India.

[3] Considering the marks as a whole and the significance of the term "INDIA" in applicant's mark, we are of the opinion that applicant's mark does not so resemble that of the opposer to be likely to cause confusion.

Decision

The opposition is dismissed.

LEACH, Member, dissenting.

Although "INDIA" possesses a geographical connotation, it does not necessarily follow that it is a "weak" mark as applied to goods of the character here involved, and, on the record presented on this case, I am not persuaded that it is weak or is for any reason lacking in distinctiveness. Moreover, since opposer is the owner of a registration of "INDIA" which issued on the Principal Register, it must here be presumed that the mark does in fact serve to identify and distinguish opposer's goods. Jenkins Publishing Company v. Metalworking Publishing Company, Inc., 137 USPQ 358 (CCPA, 1963); Contour Chair-Lounge Co., Inc. v. The Englander Company, Inc., 139 USPQ 285 (CCPA, 1964); The Joseph & Feiss Company v. Joseph Kanner Hat Co., Inc., 143 USPQ 297 (CCPA, 1964).

The record in this case fails to show that anyone other than the parties hereto uses the word "INDIA" in connection with the sale of piece goods or clothing. And, considering that "INDIA" constitutes the entire mark of opposer and twice appears prominently in applicant's, it is my opinion that these marks create substantially the same commercial impression and, hence, that their contemporaneous use for the specified goods would be likely to cause confusion or mistake or to deceive.

I would sustain the opposition.

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54 CCPA

Court of Customs and Patent Appeals

In re SURREY

Appl. No. 7536 Decided Dec. 15, 1966

PATENTS

1. Specification—Sufficiency of disclosure (§ 62.7)

It is clear from 36 U.S.C. 112 that Congress intended adequate disclosures to support claims; statute requires that description be concise as well as full; thus, applicant, who discloses a generic invention, is not required to give an example of every species falling within it, or even to name every such species, it being sufficient if disclosure teaches those skilled in the art what the invention is and how to practice it.

2. Patentability—Utility (§ 51.75)
Specification—Sufficiency of disclosure (§ 62.7)

Disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe how to use those compounds.

3. Specification—Sufficiency of disclosure (§ 62.7)

Nothing is gained by including repetitive examples in specification, all asserting generally the same kind of biological activity, for each compound dominated by claim; however, applicant must provide reasonable assurance to one skilled in the art, as by adequate representative examples, that compounds falling within scope of claim will possess the asserted usefulness.

Particular patents—Thiazolidones

Surrey, 4-Thiazolidones and Oxide Derivatives Thereof, claim 17 of application refused.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Alexander R. Surrey, Serial No. 120,501, filed June 29, 1961; Patent Office Group 120. From decision rejecting claim 17, applicant appeals. Affirmed; Smith, Judge, dissenting with opinion.

LAURENCE & LAURENCE (DEAN LAURENCE and HERBERT I. SHERMAN of counsel) all of Washington, D. C., for appellant.

CLARENCE W. MOORE (JOSEPH SCHIMMEL of counsel) for Commissioner of Patents.

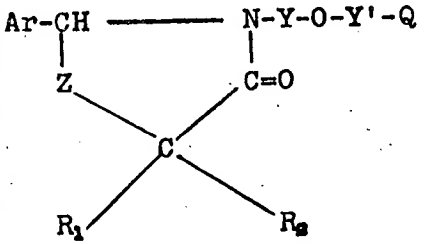
Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

WORLEY, Chief Judge.

This appeal is from the decision of the Board of Appeals affirming the rejection of claim 17 in appellant's application [1] entitled "4-Thiazolidones and Oxide Derivatives Thereof."

The subject matter is evident from the claim, to which we have added emphasis to indicate the particular language giving rise to the issues of sufficiency of disclosure and new matter before us:

17. A compound of the formula



where *Ar is a member of the group consisting of phenyl, maphthyl, biphenylyl, furyl, pyridyl, pyrimidyl, thiazolyl, oxazolyl, quinolyl, isoquinolyl and thienyl radicals and such radicals substituted by one to three substituents selected from the group consisting of lower-alkyl, lower-alkoxy, lower-alkylmercapto, lower-alkylsulfonyl, halo, trifluoromethyl, nitro, amino, lower-alkylamino, lower-alkanoylamino, phenoxy, benzyloxy, hydroxy, phenylmercapto, benzyl and 4-chlorophenoxy*, Y is polycarbon-lower-alkylene having from two to six carbon atoms and having its two free valence bonds on different carbon atoms, Y' is a member selected from the group consisting of a direct linkage and lower-alkylene having from one to six carbon atoms, Q is a member selected from the group consisting of lower-alkyl having from one to six carbon atoms, unsubstituted-phenyl and phenyl substituted by one to three substituents selected from those given hereinabove for the aromatic radical at the 2-position of the thiazolidone ring, Z is a member selected from the group consisting of S, SO and SO_2, and R_1 and R_2 each is selected from the group consisting of hydrogen and lower-alkyl.

In summarizing the examiner's rejection the board stated:

Claim 17 stands rejected as failing to define the invention in the manner required by 35 U.S.C. 112. The examiner considers that the compounds recited in claim 17 lack adequate representative basis in the disclosure and that the claim is accordingly too broad and unduly speculative.

As an example of the contended lack of adequate representative basis in the disclosure for the compounds recited in the Markush group of the appealed claim the examiner cites the oxazolyl member. The examiner states that the claimed compounds include the class of 2-oxazolylthiazolidones wherein the oxazolyl radical may be substituted by one to three substituents selected from the group consisting of lower alkyl, lower alkoxy, lower alkylmercapto, lower alkylsulfonyl, halo, trifluoromethyl, nitro, amino, lower alkylamino, lower alkanoylamino, phenoxy, benzyloxy, hydroxy, phenylmercapto, benzyl and 4-chlorophenoxy. The examiner states that the only support in the specification for an unsubstituted oxazolyl compound is the (4-oxazolyl) compound disclosed * * *, its oxide * * * and its dioxide * * *. The examiner states that there are no examples of

[1] Serial No. 120,501, filed June 29, 1961. Claims 2-11 of the application have been allowed.

a substituted oxazolyl compound to support the various classes of oxazolyl compounds having 1 to 3 of the various substituents listed in the appealed claim.

The examiner further states that there are no representative examples of substituted pyrimidyl, quinolyl, isoquinolyl, or thiazolyl compounds, and that many of the classes of naphthyl, biphenylyl, furyl, thienyl and pyridyl are not represented.

It agreed with the examiner's finding that the specification did not adequately teach and fully illustrate the subject matter of the claim, stating that it could not find wherein the specification does in fact give examples to support many of the various classes of carbocyclic and heterocyclic "Ar" radicals having 1-3 substituents of the nature listed in the claim.

[1] Whether a broad claim to chemical compounds is sufficiently supported by the disclosure as a whole, including compounds named and examples given in the specification, has frequently been considered by this court. In re Cavallito (PA 6502), 48 CCPA 711, 282 F.2d 357, 127 USPQ 202; In re Cavallito (PA 6508), 48 CCPA 720, 282 F.2d 363, 127 USPQ 206; In re Sus, 49 CCPA 1301, 306 F.2d 494, 134 USPQ 301; In re Cavallito (PA 6822), 49 CCPA 1335, 306 F.2d 505, 134 USPQ 370. That Congress intended adequate disclosures to support claims is clear from the positive language of 35 U.S.C. 112:

§ 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using, it, *in such full, clear, concise, and exact terms* as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

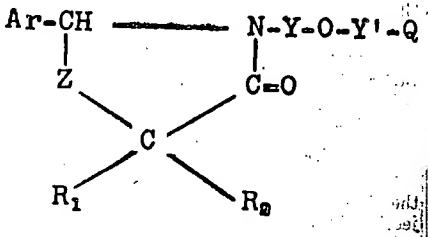
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. * * * (Emphasis supplied).

In applying those requirements, we stated in In re Cavallito (PA 6508 and 6822, 127 USPQ at 209, 134 USPQ at 372):

* * * The sufficiency of a disclosure depends not on the number but rather on the nature of the claimed compounds per se and the nature of the supporting disclosures. If a claim covers compounds which are closely related, a comparatively limited disclosure may be sufficient to support it. If, however, the claim covers compounds which are related only in some structural respects, a more extensive supporting disclosure may be necessary to support it. Moreover, the selection of the examples and other exemplary material used as the disclosure to support a claim must be adequately representative of the area covered by it. In some instances a limited disclosure which is typical of various areas covered by a claim may be of greater value in determining the patentable characteristics of the claimed compounds than a more extensive disclosure would be if related only to a limited portion of the area.

We turn, then, to an analysis of the "written description of the invention" in appellant's specification to determine if it does provide adequate representative basis for the compounds of the claim.

Appellant discloses certain 2-aromatic-4-thiazolidones, their -1-oxides and -1,1-dioxides having the formula



While the radical "Ar" is defined in the specification as an aromatic radical possessing the carbocyclic or heterocyclic ring structures substantially as enumerated in claim 17, preferred compounds are said to be those in which "Ar" is a radical of the benzene series, viz, a phenyl radical. Appellant then describes the nature and scope of the substituents which may be placed on the phenyl radical, again in language corresponding, for the most part, to that employed in claim 17. Appellant then states:

The other aromatic radicals, e.g., naphthyl, biphenylyl, furyl, pyridyl, thienyl, etc., radical can be unsubstituted or substituted by substituents as illustrated above as substituents of the phenyl radical.

After further defining the nature and scope of Y, Y', Q, Z, R_1 and R_2 appearing in claim 17, about which no question is raised here, and also setting forth in general terms the procedure employed to synthesize the compounds, appellant devotes most of the remainder of his specification to details as to how some 150 specifically named compounds "were prepared" or "can be prepared" by following the steps of four examples. Appellant has included in the record a convenient summary of that specific disclosure, our adaptation of which follows:

Table A—Carbocyclic Compounds which "Were Prepared"

Ar	Z	Y-O-Y'-Q	$R_1=R_2=H$
3,4-Cl_2-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
2-Cl-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
4-Cl-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
2,4-Cl_2-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
4-CH_3O-phenyl	S, SO_2	$(CH_2)_2OCH_3$	
phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
3,4-Cl_2-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
3,4-Cl_2-phenyl	S, SO	$(CH_2)_2OC_2H_5$	
3-Cl-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
4-(4-$NO_2C_6H_4O$)-phenyl	S	$(CH_2)_2OCH_3$	
4-n-C_4H_9O-phenyl	S, SO	$(CH_2)_2OCH_3$	
4-NO_2-phenyl	S, SO, SO_2	$(CH_2)_2OCH_3$	
3,4-$(CH_3)_2$-phenyl	S, SO		

Table B—Carbocyclic Compounds which "Can Be" Prepared

Ar	Z = S, SO or SO_2	Y-O-Y'-Q	$R_1 = R_2 = H$
2-CH_3-phenyl		$CH_3CH(CH_3)OCH_3$	
4-i-C_3H_7-phenyl		$(CH_2)_2OC_3H_7$-i	
4-I-phenyl		$(CH_2)_2OC_4H_9$-n	
3-Br-phenyl		$(CH_2)_2OC_6H_{13}$-n	
2, 4, 6-Cl_3-phenyl		$(CH_2)_2OCH_3$	
4-CH_3O-phenyl		$(CH_2)_2OC_2H_5$	
3-C_2H_5O-phenyl		$(CH_2)_2OC_3H_7$-n	
3, 4-$(CH_3O)_2$-phenyl		$(CH_2)_2OC_2H_5$	
3-Cl-4-CH_3O-phenyl		$(CH_2)_2OCH_3$	
4-n-C_3H_7S-phenyl		$CH_2CH(C_2H_5)OC_2H_5$	
4-n-$C_4H_9SO_2$-phenyl		$(CH_2)_2OCH_3$	
3-CF_3-phenyl		$(CH_2)_2OC_2H_5$	
4-CH_3CONH-phenyl		$(CH_2)_2OCH_3$	
4-NH_2-phenyl		$(CH_2)_2OCH_3$	
4-n-C_4H_9NH-phenyl		$(CH_2)_2OCH_3$	
4-C_6H_5O-phenyl		$(CH_2)_2OC_2H_5$	
3-$C_6H_5CH_2O$-phenyl		$(CH_2)_2OC_2H_5$	
2-HO-phenyl		$(CH_2)_2OCH_3$	
4-C_6H_5S-phenyl		$(CH_2)_2OCH_3$	
3-$C_6H_5CH_2$-phenyl		$(CH_2)_2OCH_3$	
4-(4-ClC_6H_4O)-phenyl		$(CH_2)_2OC_2H_5$	

Table C—Carbocyclic and Heterocyclic Compounds which "Can Be" Prepared

Ar	Z = S, SO, or SO_2	Y-O-Y'-Q	R_1	R_2
2-naphthyl		$(CH_2)_2OCH_3$	CH_3	H
4-biphenylyl		$(CH_2)_4OCH_2C_6H_5$	H	H
2-furyl		$(CH_2)_2OCH_3$	H	H
3-pyridyl		$(CH_2)_2OCH_3$	H	H
4-pyridyl		$(CH_2)_2OCH_2CH_2C_6H_5$	C_2H_5	H
3-thienyl		$(CH_2)_2OCH_2C_6H_4$-4-Cl	H	H
2-thienyl		$(CH_2)_2OCH_3$	CH_3	CH_3
2-C_2H_5O-1-naphthyl		$(CH_2)_2OC_6H_5$	H	H
5-NO_2-2-furyl		$(CH_2)_2OC_6H_3$-3, 4-Cl_2	H	H
5-Cl-3-pyridyl		$(CH_2)_2OCH_3$	H	H
3, 4, 5-Br_3-2-thienyl		$(CH_2)_2OC_6H_4$-4-OCH_3	C_2H_5	C_2H_5
5-pyrimidyl		$(CH_2)_2OCH_3$	H	H
4-thiazolyl		$(CH_2)_2O(CH_2)_4C_6H_5$	H	H
4-oxazolyl		$(CH_2)_2O(CH_2)_2C_6H_4$-Cl	H	H
3, 4-Cl_2-phenyl		$(CH_2)_2OCH_3$	CH_3	H
3-quinolyl		$(CH_2)_2OCH_3$	H	H
3, 4-Cl_2-phenyl		$(CH_2)_2OCH_3$	n-C_3H_7	H
3, 4, 5-$(CH_3O)_3$-phenyl		$(CH_2)_2OCH_3$	H	H
3-isoquinolyl		$(CH_2)_2OCH_3$	H	H

Appellant urges that his specification does contain a "written description" of the invention which is in sufficiently "full, clear, concise and exact terms" as to satisfy the requirements of Sec. 112. He contends that the examiner and board looked only to the specific examples present in the specification, and did not consider the entire disclosure of the application. While appellant concedes the description conceivably might have been fuller, the statute also requires the description to be "concise" and, according to appellant, it "is undisputed that the methods of preparation given would enable any chemist to make any compound within the scope of the claims."

On that narrow aspect of the issue, we agree with appellant. As we stated in In re Grimme, 47 CCPA 785, 274 F.2d 949, 124 USPQ 499, 502:

> * * * It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it.

Here it would appear to serve no useful purpose to lengthen the disclosure further with examples of compounds which "can be prepared," or to delineate further the 2-heterocyclic or carbocyclic thiazolidones which appellant contemplates. When one considers the specific examples in Table C above along with appellant's statement in his specification that those aromatic radicals can be substituted with the same substituents exemplified for the phenyl radical, we think the requirement that there be a full, yet concise, disclosure of the claimed compounds has been met. No question has been raised that the necessary intermediates[2] obviously contemplated by appellant to be used in synthesizing the 2-aromatic thiazolidones are not in fact known to those skilled in the art, or that one of ordinary skill would have any difficulty employing any of them in the particular synthesis procedure appellant has developed.

However, the examiner and board have given further reasons in support of the rejection under section 112 which we think, under the circumstances here, requires affirmance of that rejection. The board stated:

> As further evidence of the undue breadth and speculative nature of appealed claim 17, the examiner points out that the only compounds actually tested which demonstrated the asserted psychomotor stimulatory and anti-convulsant properties were those having the 3,4-dichlorophenyl substituent at the 2-position on the thiazolidone nucleus, which substituent is designated "Ar" in the appealed claim. The examiner notes that no compounds wherein "Ar" is heterocyclic were tested. We agree with the examiner's contention that there is no reasonable basis for a conclusion that all of the diverse compounds covered by the claim would be equivalent to the small and homogeneous group actually tested, and that the appealed claim is so broad as to cover compounds the utility or operativeness of which for the disclosed purpose is speculative.

[2] Appellant prepares his 2-aromatic thiazolidones by reacting an azomethine of the formula ArCH=N-Y-O-Y'-Q with an α-mercaptoacetic acid of the formula $HSC(R_1)(R_2)COOH$. The azomethine compounds, in turn, are prepared by reacting an aromatic aldehyde, ArCHO, with an amine, NH_2-Y-O-Y'-Q. The existence of such aromatic aldehydes, substituted by 1-3 radicals of the type enumerated in claim 17, has not been questioned.

With regard to the usefulness of his compounds, appellant's specification states:

> The physical embodiments of my invention have been tested by standard pharmacological evaluation procedures and found to possess psychomotor stimulatory properties and anticonvulsant properties. These compounds also have the additional advantageous property of having relatively low toxicity. The compounds where Z is S have further utility as intermediates for the preparation of the compounds where Z is SO or SO_2. Also the compounds where Z is SO can be used as intermediates for the preparation of the compounds where Z is SO_2.
>
> * * *
>
> My compounds of formula I, as illustrated by the foregoing examples, are of particular interest because they possess psychomotor stimulatory properties, exhibit anticonvulsant activity and have low toxicity. When administered orally to mice * * *, they were found to have psychomotor stimulatory properties at dose levels of about 25 to 400 mg. per kg. of body weight. For example, the following compounds produced marked stimulation at doses of about about 200 mg. per kg.: 2-(3,4-dichlorophenyl)-3-(2-methoxyethyl)-4-thiazolidone, 2-(3,4-dichlorophenyl)-3-(3-methoxypropyl)-4-thiazolidone, 2-(3,4-dichlorophenyl)-3-(2-methoxyethyl)-4-thiazolidone-1-oxide, 2-(3,4-dichlorophenyl)-3-(3-methoxypropyl)-4-thiazolidone-1-oxide, 2-(3,4-dichlorophenyl)-3-(2-methoxyethyl)-4-thiazolidone-1, 1-dioxide and 2-(3,4-dichlorophenyl)-3-(3-methoxypropyl)-4-thiazolidone-1,1-dioxide.
>
> The compounds of my invention protect against metrazol and maximal electro shock convulsions when tested by standard procedures in mice, e.g., the calculated dose (PD_{50}) of 2-(3,4-dichlorophenyl)-3-(2-methoxyethyl)-4-thiazolidone-1-oxide for protecting 50% of the animals against maximal electroshock was 265 ± 29.4 mg. per kg. orally and 116 ± 26.5 mg. per kg. intraperitoneally; similarly, this compound was found to have an oral PD_{50} of 76 ± 13.0 mg. per kg. and an i.p. PD_{50} of 51 ± 10.7 mg. per kg. when administered to mice prior to challenge with metrazol (50 mg. per kg. i.v.).
>
> As illustrative of the low toxicities of my compounds, the following compounds were found to have approximate acute oral toxicities (ALD_{50}) in mice in the range of about 1000 to 4000 mg. per kg.: 2-(3,4-dichlorophenyl)-3-(2-methoxyethyl)-4-thiazolidone, 2-(3,4-dichlorophenyl)-3-(2-methoxyethyl)-4-thiazolidone-1-oxide, 2-(3,4-dichlorophenyl)-3-(3-methoxypropyl)-4-thiazolidone-1-oxide and 2-(3,4-dichlorophenyl)-3-(3-methoxypropyl)-4-thiazolidone-1,1-dioxide.

In view of the above disclosure in his specification, appellant contends the additional reasons given by the board are untenable with respect to an issue under section 112, which requires that the written description teach those skilled in the art "how to use" the invention. The specification, appellant says, does just that—if the examiner and board had doubts as to the operativeness of the compounds for the disclosed purpose, a rejection under 35 U.S.C. 101 should have been made.

[2] We doubt whether simply denoting the reasons given by the examiner and board as applying to a section 112 or section 101 rejection would have clarified matters further for appellant, particularly where he had notice of those reasons prior to the board's decision and the examiner's Answer.[3] Manifestly, a disclosure which does not adequately establish compounds as use-

[3] The record shows that, in the final rejection, the examiner said:

> * * * The claim is so broad as to be speculative as to utility and mere listing of possibilities as a basis of the terms does not avoid the speculativeness of the disclosure.

As noted above, the board has summarized the examiner's position as set forth in his Answer.

In a reply brief to the examiner's Answer, appellant countered the examiner's reasoning with the statement:

> * * * The examiner reverses the usual position of the Patent Office (supported by many CCPA and other authoritative holdings) that analogous chemical structures can generally be presumed to have similar properties; instead here the examiner takes the position that the groups involved are so diverse in character as to raise doubts as to their imparting like properties. * * *

As will appear, we do not regard the present compounds to be "analogous."

ful for an asserted purpose does not adequately describe "how to use" those compounds either. Moreover, as we stated in In re Cavallito (PA 6502, 127 USPQ at 204-205):

> * * * We agree with the board that the possible existence of compounds falling within the scope of the claims, but not having the utility set forth in appellant's specification, may properly be considered in connection with a rejection on undue breadth.
>
> * * *
>
> * * * It is not necessary to determine whether the presence of one or two useless compounds within the scope of a claim to a chemical compound would render it unpatentable, but where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful. That is especially true where, as here, the claims are not drawn in terms of a recognized genus but are directed to a more or less artificial selection of compounds. There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others. * * *

[3] Absent supporting evidence in the record, we are not prepared to say that the diverse classes of compounds embraced by the appealed claim are so closely related or analogous that extrapolation of the activity of the 2-dichlorophenyl compounds to the 2-heterocyclic compounds is warranted. Of course, nothing of consequence is to be gained by including repetitive examples in the specification, all asserting generally the same kind of biological activity, for each and every compound dominated by the claim. Such a requirement would tend to place an undue burden on an applicant and prevent early filing of an application. We think, however, appellant here has failed to provide those of ordinary skill in the art, the Patent Office and this court, reasonable assurance, as by adequate representative examples, that the compounds falling within the scope of the claim will possess the asserted usefulness. We find no unequivocal statement in appellant's specification or in his brief here that compounds other than those actually tested are anticonvulsants or psychomotor stimulants. Appellant simply says the "*physical embodiments*" of his invention "have been tested * * * and found to possess" the named properties. Those "physical embodiments," insofar as the record shows, are the 3,4-dichlorophenyl compounds and perhaps other substituted phenyl compounds which "were prepared," not those which "can be prepared." It seems to us that one skilled in this art would not necessarily be taught by the written description of the invention that any 2-aromatic thiazolidone dominated by the claim, or their 1-oxides or 1,1-dioxides, would likely possess the asserted usefulness, but rather that only the 2-substituted phenyl thiazolidone would be so useful. See In re Sus; In re Cavallito (PA 6822).

The view we take of this appeal makes it unnecessary to consider whether the expression "lower-alkanoylamino" employed in claim 17 constitutes new matter.

The decision is *affirmed.*

MARTIN, Judge, participated in the hearing of this case but died before a decision was reached.

SMITH, Judge, dissenting.

The statutory commands of 35 U.S.C. 112 each refer to "the invention" for which a patent is sought. Here the persistent failure to determine and articulate "the invention" which is in issue, as expressly required by section 112, has compounded the confusion for the court. Appealed claim 17 is directed to "a compound" having a formula which by reason of its statement in Markush form actually encompasses what the solicitor's brief refers to as "a number of compounds of diverse structure running into six or seven figures." However, "the invention" with which we are here concerned may be something more than "a compound" as claimed in appealed claim 17. Thus, appellant states in his specification:

> This invention relates to 2-aryl-4-thiazolidones, -1-oxides and -1,1-dioxides, and is particularly concerned with certain 3-substituted derivatives thereof and methods for the preparation of such derivatives.
>
> * * *
>
> The physical embodiments of my invention have been tested by standard pharmacological evaluation procedures and found to possess psychomotor stimulatory properties and anticonvulsant properties. These compounds also have the additional advantageous property of having relatively low toxicity. The compounds where Z is S have further utility as intermediates for the preparation of the compounds where Z is SO or SO_2. Also the compounds where Z is SO can be used as intermediates for the preparation of the compounds where Z is SO_2.

It seems clear to me that the rejection here is fatally defective. In the examiner's answer it is stated:

> Claim 17 stands finally rejected as failing to define the invention properly, 35 U.S.C. 112. Specifically, the claim is broader than the disclosure * * *.

This rejection was affirmed by the board. As I understand the rationale of the majority opinion on what it terms "that narrow aspect of the issues," the majority agrees with appellant. Thus the specification contains a "written description of the invention," and it sets forth "the manner and process of *making* and *using* it, in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same * * *" 35 U.S.C. 112. Further, there is no argument that the appealed claim fails to particularly point out and distinctly claim the subject matter which the appellant regards as his invention. This, it seems to me, requires a reversal of the only ground of rejection which has been stated with the particularity required by 35 U.S.C. 132.

There is, however, an indistinct and somewhat murky ground of rejection which has its genesis in the above quoted portion of the specification where reference is made to the "psychomotor stimulatory properties and anticonvulsant properties" of "physical embodiments" of the invention which have "relatively low toxicity." Apparently considering these statements as being "the invention," the examiner's answer states as a further ground of rejection:

> The claim is also regarded as being unduly speculative because the relatively few compounds actually prepared and tested are not adequately representative of the diverse classes of compounds which are claimed (In re Cavallito et al., 127 USPQ 202; In re Grant, 134 USPQ 248; In re Cavallito et al., 1962 C. D. 607, 134 USPQ 370).

It seems clear that what the examiner has done is to confuse the field of asserted utility of the claimed "compound" with "the invention" being claimed. This appears rather clearly from further portions of the examiner's answer which state:

> The disclosure is also regarded as being unduly speculative with regard to utility. The compounds are stated to possess psychomotor stimulatory properties and anticonvulsant properties (specification page 1, lines 15-19). The compounds actually demonstrating such utility are shown at pages 16-17, beginning with the paragraph bridging the two pages. All of these compounds have the 3,4-dichlorophenyl substituent at the 2-position on the thiazolidone nucleous, which substituent is designated as "Ar" in the appealed claim. No compounds wherein "Ar" is heterocyclic are tested. There is no reasonable basis for the conclusion that all of the diverse compounds embraced by the claim would be equivalent to the very small and homogeneous group actually demonstrating such properties.
>
> * * * In the field of therapeutics, where prediction is very limited, the scope of the claims must correspond closely to the compounds sufficiently closely related to those actually tested that their properties would be expected to be similar. The diverse classes of compounds embraced by the appealed claim are not so closely related that extrapolation of the activity of the dichlorophenyl compound to the various heterocycles is warranted. (In re Oppenauer, 62 USPQ 297; Am. Chem. Paint v. Firestone, 48 USPQ 405).

The board formulated its own statement of the rejection which, however, does not seem to me to be quite the same as the examiner's rejection. The board stated:

> Claim 17 stands rejected as failing to define the invention in the manner required by 35 U.S.C. 112. The examiner considers that the compounds recited in claim 17 lack adequate representative basis in the disclosure and that the claim is accordingly too broad and unduly speculative.

Later in its opinion the board amplifies on its view of the rejection and states:

> * * * We agree with the examiner's contention that there is no reasonable basis for a conclusion that all of the diverse compounds covered by the claim would be equivalent to the small and homogeneous group actually tested, and that the appealed claim is so broad as to cover compounds *the utility or operativeness of which for the disclosed purpose is speculative.* [Emphasis added.]

From the foregoing it seems to be that the real basis of the rejection is the failure of appellant to establish a rea-

sonable basis for assuming that all compounds coming within the appealed claim would have the utility or operativeness set forth for "the small and homogeneous group actually tested," in other words, a failure to establish utility commensurate in scope with the appealed claim. 35 U.S.C. 101. The requirements of section 101 and section 112 should not be confused. Whether the specification teaches one of ordinary skill in the art how to make and use the invention presents a different and independent inquiry than whether the use disclosed satisfies section 101 or whether the invention described is useful. Where the objection is, in effect, that it is not believed that the invention is operable as described or useful for the asserted purpose it seems to me that section 101 is the basis for the rejection. Whether the invention is useful, within the meaning of the law, is independent of the fact that the specification teaches one of ordinary skill in the art how to make and use the invention. Nor does satisfying section 112 prove section 101 is satisfied.

It is apparent that a rejection based on "undue breadth" of the claims fails to define which section of the Patent Act is being relied on. As the examiner and board specified that the rejection is based on section 112, it seems to me our deliberations should be confined to the consideration of the reasoning of record relevant to a rejection properly based on that section. Accordingly, as I find this reasoning to be insufficient to support a rejection under section 112, I would reverse the decision of the board.

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54 CCPA

Court of Customs and Patent Appeals

ENGELHARDT v. JUDD, DRUKKER, AND BIEL

Appl. No. 7642 Decided Dec. 15, 1966

PATENTS

1. Interference—Burden of proof — Involving applicant and patentee (§ 41.055)

Since junior party's application was filed subsequent to issuance of senior party's patent, burden is on junior party to prove actual reduction to practice of a compound of counts beyond a reasonable doubt.

2. Interference—Reduction to practice—Tests (§ 41.758)

Reference to dosing humans in specification does not preclude inventor from proving actual reduction to practice of a drug by successful utility testing on standard experimental animals.

3. Evidence — Judicial notice (§ 36.20)

Court does not take judicial notice of asserted facts in brief which are not matters of common knowledge.

4. Interference — Reduction to practice —In general (§ 41.751)

Compound may conceivably be useful for many different specific purposes, any one of which may suffice to show practical, substantial utility for a compound of interference count unlimited as to use.

5. Interference—Priority (§ 41.70)

Interference — Reduction to practice — In general (§ 41.751)

Patentability — Anticipation — Prior knowledge, use or sale (§ 51.223)

Actual reduction to practice may be proved regardless of whether patent application constructively reducing same invention to practice is ever filed, and the actual reduction might serve to invalidate patent of subsequent inventor under 35 U.S.C. 102(g), unless prior inventor abandoned, suppressed, or concealed invention which he had been first to reduce to practice.

6. Interference — Reduction to practice—Tests (§ 41.758)

Since court is considering claims to compounds, court is not concerned with fact that, in establishing an actual reduction to practice, applicant successfully demonstrated utility of compound in animals for somewhat different pharmaceutical purposes than those asserted in his specification.

7. Interference—Priority (§ 41.70)

Each case of alleged suppression and concealment under 35 U.S.C. 102(g) must be decided on its own facts.

8. Interference—Priority (§ 41.70)

Inventor of new series of compounds should not be forced to file applications piecemeal on each new member as it is synthesized, identified, and tested for utility; reasonable amount of time should be allowed for completion of research project on whole series of new compounds, and a further reasonable time should be allowed for drafting and filing patent applications, without subjecting prior inventor or his assignee to risk of forfeiture of patent rights due to concealment or suppression of invention; however, delay of two years and three months in filing application is unreasonable and inexcusable, considering invention to be only one compound of series which applicant actually synthesized and tested; to extent that invention is regarded as whole series of compounds disclosed and claimed in application and in opponent's patent, applicant testified that, at time patent issued, over two years after applicant's synthesis of one compound of series, he had no plans for making or testing other members of series; applicant was spurred into activity by actual knowledge of issuance of patent; applicant's right to patent was forfeited under 35 U.S.C. 102(g).

9. Interference—Priority (§ 41.70)

Courts are reluctant to expand forfeiture doctrine of Mason v. Hepburn, 13 App. D.C. 86.

Particular patents — Dibenzocycloheptenes

2,985,660, Judd, Drukker, and Biel, 5-Heterocyclic-5-H-Dibenzo (a, d) Cycloheptenes, awarded priority against Engelhardt application.

Appeal from Board of Patent Interferences of the Patent Office.

Patent interference No. 92,376 between Edward L. Engelhardt, application, Serial No. 115,910, filed June 9, 1961, and Claude I. Judd, Alexander E. Drukker, and John H. Biel, Patent No. 2,985,660, issued May 23, 1961. From decision awarding priority to Judd, Drukker, and Biel, Engelhardt appeals. Affirmed.

JOHN P. FLOYD, New York, N. Y. (ALBERT W. RINEHART, Washington, D. C., and RAYMOND UNDERWOOD, H. E. WESTLAKE, JR., and I. LOUIS WOLK, all of Rahway, N. J., of counsel) for appellant.

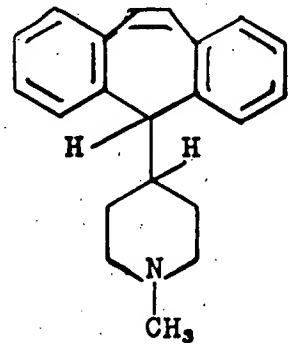
HERBERT S. SYLVESTER (RICHARD R. STEVENS and GEORGE H. MORTIMER of counsel) all of New York, N. Y., for appellees.

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

ALMOND, Judge.

This is an appeal from the decision of the Board of Patent Interferences awarding priority of invention in Interference No. 92,376 to senior party Judd, Drukker, and Biel (hereinafter Judd), who are involved in this proceeding on the basis of their patent No. 2,985,660, which issued May 23, 1961, on an application filed April 29, 1960. Junior party Engelhardt filed his application serial No. 115,910 on June 9, 1961, admittedly after seeing a copy of the patent granted to Judd.

Count 1 is representative and is directed to a specific compound, 5-(N-methyl-4-piperidyl)-5H-dibenzo [a, d] cycloheptene, which has the following structural formula:



[1] The junior party took testimony in the proceeding while the senior party relied on the filing date of the Judd patent. Since the Engelhardt application was filed subsequent to issuance of the senior party's patent, it is well settled that the burden is on the junior party to prove actual reduction to practice of a compound of the counts beyond a reasonable doubt.

The board recognized this and credited Engelhardt with an actual reduction to practice no later than March 3, 1959, two years and three months prior to his filing date. The board commented as follows in holding that the junior party synthesized and analyzed his compounds and successfully tested their usefulness as drugs:

> We have no doubt upon the evidence that Zell under Engelhardt's instructions and supervision produced the compound of Count 1 and its maleic salt according to Count 2 and identified them upon satisfactory experimental and analytical evidence * * * and sent the maleic salt to the Pharmacological Laboratories for testing. Neither do we have any doubt * * * that the compound was tested for toxicity on mice, and then for antihistamine effect on guinea pigs and for serotonin antagonism by the rats foot edema test, and that the latter tests both showed "effect." * * * All of the work was completed before March 3, 1959. * * *

The board recognized that Archer v. Papa, 46 CCPA 835, 265 F.2d 954, 121 USPQ 413, holds that successful use of a compound on laboratory animals may be sufficient proof of utility to estab-

Miller Studio, Inc., which registered claims on "M86 Flirting Fish, Girl," and "M86 Flirting Fish, Boy," with the United States Copyright Office. See Miller affidavit and Exhibits A and B attached thereto.

3. In 1963 certain wall plaques (Exhibit 3a attached to the complaint) depicting ballerinas were conceived and designed and, in January 1964, introduced to the trade and Miller Studio, Inc. registered a claim on "M81 Ballet Trio" with the United States Copyright Office. See Miller affidavit and Exhibit C attached thereto.

4. Adequate copyright notices appear on each of plaintiff's wall plaques.

5. In the summer of 1964, identical copies of plaintiff's wall plaques were being offered to the trade by Pacific Import Co., Inc. and a notice to desist was sent to defendant by plaintiff's attorneys on or about July 31, 1964. See Exhibit D attached to the Miller affidavit.

6. The defendant, by failing to answer or to controvert plaintiff's request for admissions,[1] has admitted the sale of plaintiff's copyrighted plaques. Fed. R. Civ. P. 36(a).

7. The plaques, distributed by defendant, appear upon examination by me to be identical copies of plaintiff's plaques.

8. The defendant gave the plaintiff no assurances that it would desist.

The defendant here may not rest upon mere allegations or denials of its pleadings but must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). This the defendant has not done.

The defendant's memorandum of law sets up the following defenses:

1. Plaintiff has not shown what was actually filed in the Copyright Office to secure registration;

2. Plaintiff should have registered these plaques as reproductions of works of art (Class H) and not as originals (Class G);

3. No proof of copying by defendant exists since the defendant's plaques were purchased in Japan; and

4. Defendant had no access to plaintiff's plaques.

[1] The affidavit of Miller with the Certificates of Registration which are attached as exhibits shows what was filed in the Copyright Office. See F. W. Woolworth Co. v. Contemporary Arts, Inc., 193 F.2d 162, 165, 92 USPQ 4, 6 (1st Cir. 1951), aff'd 344 U.S. 228, 95 USPQ 396 (1952). The Certificate of Registration is prima facie evidence of the facts stated therein, 17 U.S.C. § 209, and in the absence of contradictory evidence is sufficient proof to establish a valid copyright, Ball, Copyright § 262 (1944), and cases cited therein. Thus, there is no merit in defendant's assertion that a defense exists because plaintiff has not shown what was actually filed in the Copyright Office. Additionally defendant has submitted no acceptable proof to substantiate its claim that the plaques should have been registered as reproductions of works of art rather than as originals.

[2] Neither does proof appear to substantiate defendant's claim that its plaques were copied from Japanese originals and not from the plaintiff's plaques. The plaintiff is not compelled to negative a claim which has not one iota of substantiation. Where, as here, the defendant has failed to show that the allegedly infringing plaques were obtained from some source other than plaintiff's plaques and, where, as here, the defendant's plaques clearly appear to be copies of plaintiff's plaques, the inference is justified that the alleged infringer copied plaintiff's plaques. Ball, Law of Copyright, § 259 at 595 (1944), citing Blackburn v. Southern California Gas Co., 14 F.Supp. 553, 29 USPQ 437 (S.D.Cal. 1936). This is the case even though the burden of proving infringement is on the plaintiff. "Where there is a substantial identity * * *, a presumption of unlawful copying by the later author arises. While the burden of proof remains on the plaintiff throughout to prove copying, the burden of going forward with the evidence under such circumstances is on the defendant, and, in the absence of any explanation by him to account for such similarities, the plaintiff is entitled to a decree on such prima facie case." Ball, Copyright § 265 (1944), citing Frank Shepard Co. v. Zachary P. Taylor Pub. Co., 193 F. 991 (2nd Cir. 1912), General Drafting Co. v. Andrews, 37 F.2d 54, 4 USPQ 72 (1st Cir. 1930), and other cases.

[3] There is no direct evidence that defendant had access to plaintiff's plaques, but in such a case as the present one, where striking similarities appear, access may be inferred. Wilkie v. Santly Bros., Inc., 91 F.2d 978, 34 USPQ 269 (2nd Cir. 1937); General Drafting Co. v. Andrews, supra. Lewys v. O'Neill, 49 F.2d 603, 9 USPQ 465 (S.D.N.Y. 1931), is inapposite since the acceptable evidence in that case clearly showed that the defendant had no access to plaintiff's work.

[4] At the hearing on this motion, the defendant claimed that the plaintiff's plaques did not contain proper notices of copyright. The claim is without merit. Notices appear on the sides of the plaques; it is not required to place the notice on the face. Coventry Ware, Inc. v. Reliance Picture Frame Co., 288 F.2d 193, 129 USPQ 83 (2nd Cir.), cert. denied 368 U.S. 818, 131 USPQ 499 (1961).

I conclude that there is no genuine issue as to any material fact.

The motion for summary judgment is granted with costs against defendant.

A motion by plaintiff for the defendant to pay certain expenses and attorney's fees because of the defendant's failure to attend and proceed with the taking of a deposition noticed by the defendant has previously been denied. Memorandum endorsed September 22, 1965.

The present application of plaintiff for an allowance for legal services is denied.

The question of damages is reserved pending report of a Commissioner, if one is to be appointed.

Settle judgment on notice.

[1] Defendant's counsel denies receipt of the plaintiff's request. However, the original request contains an admission of service as follows: "Copy Received July 7, 1965 Ruth W. Price (For Harry Price)." Ruth W. Price appears to be the wife of Harry Price. I see no reason to set aside the notice to admit and no such motion has been made.

53 CCPA

Court of Customs and Patent Appeals

In re WESSLAU

Appl. No. 7447 Decided Nov. 26, 1965

PATENTS

1. Patentability—Composition of matter (§ 51.30)

Claims to process of polymerizing ethylene are not rejected on theory that applicant's catalyst system can be met merely by substitution of groups from two prior patents on the corresponding components of a third prior system since no one of the references suggests such a substitution, quite apart from the result which would be obtained thereby; such piecemeal reconstruction of prior art patents in light of applicant's disclosure is contrary to 35 U.S.C. 103.

2. Patentability—Invention—In general (§ 51.501)

Question in cases within ambit of 35 U.S.C. 103 is whether subject matter as a whole would have been obvious to one of ordinary skill in the art following teachings of prior art at time invention was made; it is impermissible within framework of section 103 to choose from any one reference only so much of it as will support a given position, to exclusion of other parts necessary to full appreciation of what reference fairly suggests to one of ordinary skill in the art.

Particular patents—Polyethylene

Wesslau, Process for the Production of Polyethylene with Narrow Distribution of the Molecular Weight, claims 35 to 43 of application allowed.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Hermann Wesslau, Serial No. 753,872, filed Aug. 8, 1959; Patent Office Group 140. From decision rejecting claims 35 to 43, applicant appeals. Reversed.

ARNOLD SPRUNG, New York, N.Y., and ARNOLD B. CHRISTEN, Washington, D. C., for appellant.

CLARENCE W. MOORE (FRED W. SHERLING of counsel) for Commissioner of Patents.

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

ALMOND, Judge.

This appeal is from the decision of the Board of Appeals affirming the rejection of claims 35-43[1] in appellant's application[2] entitled "Process for the Production of Polyethylene With Narnow Distribution of the Molecular Weight." No claims have been allowed.

The invention relates to a process of polymerizing ethylene utilizing a Ziegler-type catalyst system to produce solid polyethylene. Both appellant and the Patent Office have treated the appealed process claims as standing or falling together, and we will do the same. Claim 35, from which the remaining claims depend, is illustrative and reads as follows:

> 35. In the process of polymerizing ethylene to a solid polymer having a high molecular weight and a narrow molecular weight distribution range, the improvement which comprises polymerizing ethylene in the presence of a polymerization catalyst con-

[1] Appellant withdrew the appeal with respect to the only product claim 44, which was drawn to a polyethylene having a narrow molecular weight distribution characterized by a nonuniformity value U of magnitude between 2 and 4.

[2] Serial No. 753,872, filed August 8, 1958.

sisting essentially of a mixture of titanium trichloride, at least one compound of tetravalent titanium $Ti(R)_4$ and at least one organic aluminum compound soluble in a liquid hydrocarbon and having the general formula $R'Al(R)_2$ in which R′ is alkyl and R is selected from the group consisting of halogen, alkoxy and aroxy radicals, wherein between said tetravalent titanium compound and said organic aluminum compound there is present in said mixture at least one halogen atom and at least one member selected from the group consisting of alkoxy and aroxy radicals.

According to appellant's disclosure, polyethylene of high molecular weight may be produced by what has become known in the art as the Ziegler polymerization process. Analysis of the polyethylene so produced has revealed that although the *average* molecular weight of the polymer is high, a fairly large proportion of the individual polymer chains have a relatively low molecular weight. These low molecular weight fractions are particularly unfavorable for such properties as impact bending strength, rubbing, and fatigue. Appellant has discovered that the proportion of the lower molecular weight chains can be reduced, thereby narrowing the molecular weight distribution, by employing a three-component catalyst system in which either the $Ti(R)_4$ or $R'Al(R)_2$ contains an alkoxide or aroxide moiety.

The references relied on are:

Anderson 2,862,917 December 2, 1958

Muehlbauer 2,905,661 September 22, 1959

Ruhrchemie (Belgian) 553,694 June 24, 1957

The Ruhrchemie patent relates to a process for producing polyethylene of a desired molecular weight employing certain specified catalyst systems. The pertinent portion of the patent specification reads as follows:

* * * when high molecular weight [polyethylene] products are to be obtained * * *, the employed mixtures consist of aluminum alkyl compounds and/or halides of aluminum alkyl with quantities of titanium trichloride of at least 0.01 mole * * * and quantities of titanium tetrachloride lower than 0.01 mole * * *; on the other hand, when materials having low molecular weight are to be obtained the employed mixtures consist of aluminum alkyl and/or halide of aluminum alkyl with more than 0.1 mole * * * of titanium tetrachloride per mole of aluminum alkyl and/or halide of aluminum alkyl, and with titanium trichloride at the rate of at least 0.1 mole, preferably 0.3-1 mole approximately per mole of aluminum alkyl and/or halide of aluminum alkyl.

The Anderson patent relates to a process of polymerizing ethylene whereby control over the weight average molecular weight of the polymer and the *molecular weight distribution* of the polymer is achieved by adhering to process conditions which insure the solubility of the ethylene during polymerization. The process employs coordination catalysts of titanium:

* * * obtained by admixing a trivalent or tetravalent titanium compound of the class consisting of titanium salts and titanium alkoxides with a compound having at least one metal-to-hydrocarbon bond, such as metal alkyls, suitable compounds being lithium aluminum alkyls, aluminum alkyls, Grignard reagents, alkyl aluminum halides, tin alkyls, etc. * * *

Anderson further states:

* * * the steady state compliance [an indicia of molecular weight distribution] will vary from 3 to 7 when the critical conditions of the process of the present invention are maintained and will rise to a range of 12 to 28 when the polymerization is carried out at conditions other than required by the process of the present invention. * * *

Muehlbauer relates to a process for producing high molecular weight polyolefins employing a two-component catalyst system consisting of certain metal halides and a compound of the formula $XAlR(OR')_2$ where X is halogen, and R and R′ are the same or different alkyl, cycloalkyl, or aryl radicals. Titanium trichloride and titanium tetrachloride are specifically disclosed as suitable metal halides.

The sole issue in this case is obviousness under 35 U.S.C. 103.

Appellant's principal contention is that:

* * * since none of the reference[s] either singly or in combination teach a control of the molecular weight distribution range by specific selection of catalyst components, or even that the nature or composition of the catalyst could have an effect on this molecular weight distribution range, the subject matter of the invention as a whole could not possibly be obvious from the references. * * *

We agree. Appellant's specification contains ten examples in which various three-component catalyst systems were utilized in the polymerization of ethylene. The systems set forth in three of these examples consisted of (1) titanium trichloride, (2) titanium tetrachloride, and (3) diethyl aluminum monochloride is various molar ratios. These fall within the catalyst systems disclosed by Ruhrchemie. The U value, which according to appellant's specification is a measure of the molecular weight distribution, ranges from 6.3 to 12.8 for such catalysts. In the remaining seven examples, catalyst systems covered only by the appealed claims were employed, with the nonuniformity value U [3] for the resultant polyethylene ranging from 2.6 to 3.9 We believe this to be a convincing demonstration that the alkoxide or aroxide moiety, when present in the catalyst systems of the appealed claims, possesses the property of conferring a significant degree of control over the ultimate molecular weight distribution of polyethylene. This property is neither taught nor suggested by the prior art.

The reasoning of the examiner and the board appears to be as follows: Ruhrchemie discloses a titanium trichloride - titanium tetrachloride - monoethyl aluminum dichloride system. This differs from appellant's system only in the latter's use of an alkoxide or aroxide group on either the tetravalent titanium or aluminum component or both. Since Anderson shows a tetravalent titanium compound containing an alkoxide group and Muehlbauer shows an aluminum compound containing an alkoxide group, appellant's catalyst system can be met merely by substitution of such alkoxide groups on the corresponding components of the Ruhrchemie system.

[1] The fallacy of this reasoning is that no one of the references *suggests* such a substitution, quite apart from the result which would be obtained thereby. Such piecemeal reconstruction of the prior art patents in the light of appellant's disclosure is contrary to the requirements of 35 U.S.C. 103. In re Rothermel, 47 CCPA 866, 276 F.2d 393, 125 USPQ 328.

[2] The ever present question in cases within the ambit of 35 U.S.C. 103 is whether the subject matter as a whole would have been obvious to one of ordinary skill in the art following the *teachings* of the prior art at the time the invention was made. It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The Anderson patent is the only reference before us which recognizes the desirability of producing polyethylene with a narrow molecular weight distribution range. Were one to follow the teachings of that patent in its entirety, he would be led to believe that control over the molecular weight distribution of polyethylene was gained independently of the catalyst system, a belief untenable in light of appellant's disclosure.

Both the board and the solicitor apparently assert the position that it is incumbent upon appellant to show that his results are outstanding as compared with the results accomplished by Anderson and Muehlbauer. If this is construed as requiring appellant to show unexpected results accruing from his claimed process, we think he has met the requirement. We perceive no teaching in the prior art of record suggesting that an alkoxide or aroxide moiety in a Ziegler-type catalytic system would produce the results obtained by appellant's process.

The decision of the board is *reversed*.

[3] Appellant's specification contains the following description of the nonuniformity value U:

* * * the so-called non-uniformity is used for characterising the range of distribution of the molecular weights. According to G. V. Schulz in H. A. Stuart's Die Physik der Hochpolymeren, 2nd vol., the macromolecule in solutions is given on page 754 as:

$$U = \frac{\overline{M}_w}{\overline{M}_n} \longrightarrow -1.$$

$\overline{M}_w$ and $\overline{M}_n$ can be calculated from the molecular weight distribution by current methods (G. V. Schulz and M. Marx: Makromolekulare Chemie XIV (1954), pages 53-64).

"driving means" that to which the signal is delivered from appellants' transducer means, and which results in driving the chart, the term must include a stepping motor which is intermittently driven in accordance with the signal. The stepping motor includes a drive shaft which projects through a plate and carries a first pinion. The first pinion is in mesh with a gear carried by a second shaft which is also mounted on the plate and which carries a second pinion. A further gear reduction results from the mesh between the second pinion and a second gear on a third shaft which is also carried by the plate. The third shaft carries a third pinion which meshes with a third gear which is mounted on a fourth shaft which carries the driving roll of the paper tape recorder.

As appellants state, if error occurs in their single signal, both their driving means and their recording means will be affected in the same manner. But the same is true of Parrish—if something affects the accuracy of the speed of measuring wheel 17, such as slippage, or if one of the gears 18 lost a tooth, both the drive means and the recorder means will be equally affected. Of course, should a tooth be lost from breaker cam 19 in Parrish, which we think the term "recording means" is broad enough to include, one system will be in error while the other one will not, but the same would be true should appellants' drive motor fail or should any of the gears between it and the drive roll lose a tooth. Finally, two shafts are required in Parrish's device to carry the rotational speed signal to the "recording means" and to the "drive means." While the disclosure in appellants' application is scanty in this regard, appellants' stylus-controlling device is clearly separate from their roll drive, and there are indications in both the specification and the drawings that separate wires convey the appellants' single signal to those two devices. Thus difficulties in the shaft going to Parrish's "drive means" would again correspond to difficulties in the wire going to appellants' chart drive.

As to claim 9, we agree with the board that the use of aligned auxiliary styluses as by Wait is an "obvious modification" of Parrish. Appellants take the position that Wait's styluses are "arranged in a group but not in alignment," and that the arrangement in alignment "permits the use of a larger number of styluses than is possible with Wait's arrangement." We see no reason why this would be so, since the bodies of Wait's styluses, which are on opposite sides of the line defined by their points on the recording paper, would seem to interfere with each other less than the bodies of appellants' styluses which are aligned in parallel on the same side of that line. At any rate, the disclosure of Wait indicates that the level of skill in the art was such that it would have been obvious to so arrange Wait's styluses to accommodate a greater number thereof.

For the foregoing reasons, the decision of the board is *affirmed*.

Court of Customs and Patent Appeals

In re GARDNER

No. 8923 Decided Apr. 5, 1973

PATENTS

1. Specification — Claims as disclosure (§62.3)

Original claim constituted a description in original disclosure equivalent in scope and identical in language to total subject matter now being claimed; nothing more is necessary for compliance with description requirement of first paragraph of 35 U.S.C. 112.

2. Pleading and practice in Patent Office — Rejections (§54.7)

Adequate support for Patent Office's assertions is essential requirement for sustaining rejection under 35 U.S.C. 112; if such support is sufficient, applicant's failure to provide rebuttal evidence would require affirmance.

3. Patentability — Utility (§51.75)

Specification — Sufficiency of disclosure (§62.7)

Absence of asserted utility may lead to rejection under either 35 U.S.C. 101 or 35 U.S.C. 112.

4. Specification — Sufficiency of disclosure (§62.7)

Absence of utility is standard to apply in determining reasonableness of Patent Office's doubts as to compliance with how-to-use requirement of 35 U.S.C. 112; there is no requirement that all claimed compounds have same degree of utility; some utility coupled with knowledge as to employment of utility is all that is necessary.

Particular patents—Compound

Gardner, Guanidinoalkylbenzodioxan Derivatives, claim 2 of application allowed.

Appeal from Board of Appeals of the Patent Office.

Application for patent of John Nicholson Gardner, Serial No. 679,670, filed Nov. 1, 1967; Patent Office Group 122. From decision rejecting claim 2, applicant appeals. Reversed.

ALAN D. LOURIE, Philadelphia, Pa. (WILLIAM A. SMITH, JR., Arlington, Va., of counsel) for appellant.

S. WM. COCHRAN (JACK E. ARMORE of counsel) for Commissioner of Patents.

Before MARKEY, Chief Judge, RICH, BALDWIN, and LANE, Associate Judges, and ALMOND, Senior Judge.

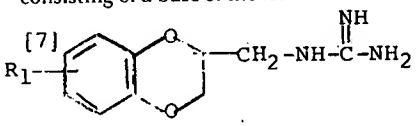
MARKEY, Chief Judge.

This appeal is from the decision of the Board of Appeals, affirming the rejection under the first paragraph of 35 U.S.C. 112 of claim 2 of appellant's application, serial No. 679,670, filed November 1, 1967, for "Guanidinoalkylbenzodioxan Derivatives."[1] We reverse.

The Invention

The application is directed to a class of guanidinoalkyl-1:4-benzodioxan compounds which are useful as antihypertensive agents. Claim 2 reads:

2. A compound selected from the group consisting of a base of the formula:



and a nontoxic, pharmaceutically acceptable acid addition salt thereof, wherein R_1 is a member of the group consisting of hydrogen, methyl, methoxy, chlorine and bromine.

The Rejection

The examiner's rejection under 35 U.S.C. 112 was couched in general terms, the claim being described as "too broad" in view of the lack of support in the specification for all the compounds encompassed by the substituent group R_1 and the floating position thereof. Express mention was made in the Answer of the lack of a "showing that all of the compounds * * * would possess the asserted utility."

The board stated:

> We think the examiner has made it clear, considering his various statements in context, that his rejection is based upon the requirements of the first paragraph of 35 U.S.C. 112 as to the "written description of the invention" and "the manner of * * * using it."

So interpreted, the rejection was sustained "for the reasons set forth in our decision in the parent case Serial No. 251,471 * * *." The fact that the present claim was considerably reduced in scope from the parent claims was not felt to render the prior reasons inapplicable. In this earlier opinion, made of record here, the basis for affirming the 112 rejection was applicant's failure to establish that the substituents on the basic guanidinoalkyl-1:4-benzodioxan nucleus had no profound effect on the antihypertensive activity of the compounds. Certain disclosure in that specification was deemed adequate support for the examiner's doubts as to the universal applicability of the asserted utility.

Opinion

We approach the rejection as structured by the board and argued by the solicitor. Accordingly, the issues lie in whether the separate but related description and how-to-use requirements of the first paragraph of 35 U.S.C. 112 have been satisfied.

Claim 2 covers a total of 17 compounds and in fact delineates a subgenus of the broad class of guanidinoalkyl-1:4-benzodioxan derivatives disclosed in the application. Only three of the five possible R_1 substituents are specifically exemplified and substitution in these examples is always in the 7-position of the benzodioxan nucleus. As pointed out by the solicitor at oral hearing, no explicit language is found in the main body of the specification corresponding to the subgenus defined by the claim.

[1] But we see no need for either additional representative examples or more definite language to satisfy the description requirement. Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure equivalent in scope and identical in language to the total subject matter now being claimed. See In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973). Nothing more is necessary for compliance with the description requirement of the first paragraph of 35 U.S.C. 112.

The major question centers around the sufficiency of the disclosure with respect to the how-to-use requirement. The primary contention of the Patent Office is that reasonable basis exists for doubting that all of the compounds encompassed by claim 2 have the asserted utility, i.e. antihypertensive activity. As in the parent case, appellant's own disclosure is said to provide the basis for doubt.

[2] Adequate support for the Office's assertions is an essential requirement for sustaining this rejection under In re Marzocchi, 58 CCPA 1069, 439 F.2d 220, 169 USPQ 367 (1971), and In re Cook, 58 CCPA 1049, 439 F.2d 730, 169 USPQ 298 (1971). If such sup-

[1] A continuation-in-part of serial No. 251,471, filed January 15, 1963, now U. S. 3,360,529.

port be sufficient, appellant's failure to provide rebuttal evidence would require affirmance. In re Fouche, 58 CCPA 1086, 439 F.2d 1237, 169 USPQ 429 (1971).

The case thus turns on the pertinent disclosures in the specification. The first statements concerning utility read:

> The generic group of compounds of this invention is characterized by having the basic guanidinoalkyl-1,4-benzodioxan nucleus which imparts antihypertensive activity to such compounds. The substituents on the basic structure may be any of those common to the art, such as those disclosed in U. S. Patent No. 2,979,511 without changing the qualitative hypotensive activity of these compounds.
>
> The compounds of this generic invention demonstrate antihypertensive activity by blockage of adrenergic nerve after intravenous administration of doses of 5-25 mg./kg. in the standard chloralose anesthecized [sic] dog procedure * * * Further quantitative properties of this group of compounds will be elaborated on hereafter.

The mentioned *quantitative* properties are set forth in this paragraph which has become the focal point of the rejection:

> The new 1:4-benzodioxan derivatives of the invention have been found to exhibit varied pharmacological activity in the animal body. Thus compounds falling within the definition of Formula 1 have been found to exercise pharmacological actions on the peripheral nervous system, particularly on the sympathetic and parasympathetic nervous systems. For instance, some of the compounds such as 2-1'-guanidinoethyl-1:4-benzodioxan have very pronounced adrenergic nerve blocking activity, some such as 5:8 - dimethyl - 2' - guanidinomethyl - 1:4 - benzodioxan have pronounced ganglion blocking activity and antihistaminic activity. All have these activities to a certain degree.

That variations in the substituents on the basic guanidinoalkyl-1:4-benzodioxan nucleus result in diverse pharmacological activities formed the basis for the Office's position that these substituents may well be critical to the asserted antihypertensive activity. Statements that "some of the compounds * * * have very pronounced adrenergic nerve blocking activity" and "some * * * have pronounced ganglion blocking activity and antihistaminic activity" were interpreted as indications that different substituents lead not just to quantitatively distinguishable effects but to qualitative differences. The fact that "all" are said to have "these activities to a certain degree" was not believed to require a conclusion of universal usefulness as antihypertensive agents, the possibility of zero effectiveness still existing.

[3] The rejection under consideration, as we have said, centers on the how-to-use requirement of § 112. It is not based on the utility requirement of § 101. But as this court pointed out in Fouche, absence of the asserted utility may properly lead to a rejection under either provision. Hence the only matter to be [4] determined is the reasonableness of the Patent Office's doubts. The standard to be applied, however, is just that—the *absence* of utility. As we said in Fouche, there is no requirement in § 112 that all of the claimed compounds have the same degree of utility. Some antihypertensive activity coupled with knowledge as to the employment of this activity is all that is necessary to satisfy the how-to-use requirement.

Considering the utility disclosure as a whole, we can find no reasonable basis for concluding that the compounds encompassed by claim 2 would not have at least some antihypertensive activity. As pointed out by appellant, the present specification contains an augmented disclosure over the parent case. The positive statements at the beginning of the specification that variances in the substituents will not qualitatively affect the asserted activity cannot be ignored. Nor is the later disclosure of varied activities inconsistent with the existence of basic antihypertensive activity. Whether the additionally described ganglion blocking activity is merely another mechanism for achieving the antihypertensive effect, as argued by appellant, or is a distinct activity is immaterial. We think the only reasonable interpretation that can be given to the concluding sentence of the controversial paragraph is that all of the compounds possess each of the aforementioned activities, although in varying degrees. A zero level of antihypertensive effectiveness is neither realistic nor consistent with the rest of the disclosure, considering particularly the specific dosages described for the compounds in general at the beginning of the specification.

The Patent Office having shown inadequate support for its doubts as to the asserted utility, the decision of the board must be *reversed.*

Court of Customs and Patent Appeals

In re KOHLER AND LITTMANN

No. 8871 Decided Apr. 12, 1973

PATENTS

1. Specification — Sufficiency of disclosure (§62.7)

All disclosure in reference must be evaluated for what it fairly teaches, not just the preferred embodiments.

Particular patents—Silicon-Iron

Kohler and Littmann, Production of Cube-on-Edge Oriented Silicon-Iron, all claims of application allowed.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Dale M. Kohler and Martin F. Littmann, Serial No. 583,459, filed Sept. 30, 1966; Patent Office Group 111. From decision rejecting all claims, applicants appeal. Reversed.

JOHN W. MELVILLE, CHARLES H. MELVILLE, GIBSON R. YUNGBLUT, and MELVILLE, STRASSER, FOSTER & HOFFMAN, all of Cincinnati, Ohio, for appellants.

S. WM. COCHRAN (RAYMOND E. MARTIN of counsel) for Commissioner of Patents.

Before MARKEY, Chief Judge, and RICH, ALMOND, BALDWIN, and LANE, Associate Judges.

MARKEY, Chief Judge.

This appeal is from the decision of the Board of Appeals, adhered to on reconsideration, affirming the rejection of all the claims of appellants' application, serial No. 583,459, filed September 30, 1966, for "Production of Cube-on-Edge Oriented Silicon-Iron," as unpatentable under 35 U.S.C. 103. We reverse.

The Invention

The invention relates to a method of producing cube-on-edge oriented silicon-iron sheet or strip for magnetic purposes. Claim 1 is illustrative:

> 1. In a method for producing cube-on-edge silicon-iron having a silicon content of from about 1.8% to about 4% and processed by steps including hot rolling to intermediate gauge, cold rolling to final gauge, decarburizing and annealing whereby to effect secondary recrystallization favoring growth of cube-on-edge nuclei by grain boundary energy, the improvement comprising in combination therewith the step of heating said silicon-iron having an oxygen content no greater than .0045% to a temperature of from 2100°F. to not more than 2400°F. immediately prior to said hot rolling step.

At the time of this invention, use of the well-known procedure outlined in the preamble of claim 1 entailed heating the slab or ingot of silicon-iron to temperatures as high as 2550°F. prior to the hot rolling step. It was disclosed by Littmann (co-inventor here) and Heck in U. S. Patent 2,559,340 that improved magnetic properties resulted from heating at this point to the highest temperature possible without "burning,"[1] i.e. from 2300° to 2550° F. Use of these extremely high temperatures, however, was attended by serious disadvantages. As pointed out in appellants' specification, the most significant was slag formation at temperatures above about 2400°F., requiring periodic shutdown of the furnace for slag removal.

Appellants' contribution lies in the discovery of a relationship between the initial oxygen content of the silicon-iron and the requisite temperature in this heating step prior to hot rolling. They have found that if the oxygen content is no greater than .0045% (preferably .0030%), the heat treatment can be conducted at a temperature of from 2100° to 2400°F. (preferably 2300° to 2400°F.) and result in an end product having magnetic properties equivalent to those previously attained by the use of the highest possible temperatures.

Appellants have agreed that all of the claims must stand or fall with claim 1, wherein this basic concept is set forth. Accordingly, we confine our review to the rejection of claim 1.

The Decision Below

The prior art relied upon consists of Littmann et al. (Littmann)[2] and Boni et al. (Boni).[3] Both patents are the property of the assignee of the present application.

As mentioned, Littmann is directed to processes for producing cube-on-edge oriented silicon steel wherein heating prior to hot rolling involves the use of temperatures up to 2550°F. The various processes to which this preliminary treatment is said to be applicable include those having the present combination of hot rolling, cold rolling, decarburizing and annealing steps. Appropriate starting materials are described simply as "silicon steel in general having a silicon content of about 2.5 to 4.0%." No particular oxygen content is dis-

[1] "Burning" is defined in the patent as "a progressive intergranular disintegration probably due to oxidation or to the migration of intergranular substances or both, and usually occurs in the neighborhood of 2600° F. in an oxidizing atmosphere."

[2] U. S. 2,599,340, issued June 3, 1952.

[3] U. S. 3,305,354, issued February 21, 1967 (filed December 17, 1964).

word "crafts" in conjunction with explanations to the effect that various handcrafted items are the product of various cottage industries, which can generally produce high quality handmade goods, albeit at a higher price than similar products produced using mass production machinery. This sort of use of "crafts" does not show that "COTTAGE CRAFTS" has a meaning identical to "cottage industry." The terms are not shown to be used interchangeably.

[3] The Examining Attorney has also submitted for the record an excerpt from the October 1, 1978 edition of the Washington Post, which states that in the Mexican countryside "there are still small studios, actually cottage crafts, where the whole family makes a certain thing * * *." This example equates the term "COTTAGE CRAFTS" with the term "small studios," not with the term 'cottage industry." Also submitted is an excerpt from the October 12, 1979 British Broadcasting Corporation Summary of World Broadcasts, the text of which states that India supplies the Soviet Union with "cottage crafts products." This is not a domestic publication, and as such it is not evidence of how the term is used in the United States. Although the quantity and variety of evidence concerning the meaning of "cottage industry" is substantial, these two relatively obscure examples of how the term "COTTAGE CRAFTS" is used are the only evidence as to the meaning of the term sought to be registered. There are no dictionary definitions of "COTTAGE CRAFTS," and no other examples from any books or periodicals. Applicant, for its part, has made of record the pertinent parts of seven dictionaries and encyclopedias dealing with the textile industry, none of which list "COTTAGE CRAFTS" as a term with a meaning in this area of commerce.

Based on the record before us we do not find that "COTTAGE CRAFTS" has any descriptive or misdescriptive significance as applied to bedspreads, quilts, and the other goods set forth in the application. It is at most suggestive of the goods. Because we find the mark to be suggestive rather that misdescriptive, we need not reach the question of whether or not anyone would be deceived by the use of this term on these goods. There is no evidence on this point in the record anyway. We do not have to ask whether the misrepresentation would materially affect the decision to purchase the goods, since a refusal under Section 2(a) was not made. Nor do we have to decide applicant's claim under Section 2(f).

Decision

The refusal to register is reversed. The evidence of distinctiveness will remain in the file, but, the request for registration under the provisions of Section 2(f) has been stricken, since it is unnecessary.

Patent and Trademark Office Board of Appeal

Ex Parte Cole, Howarth, and Reading

Opinion dated May 31, 1983

PATENTS

1. Claims — Duplicate or redundant (§20.40)

Nothing in 35 USC 112 prohibits minor overlap of claims within four corners of same application.

2. Patentability — Utility (§51.75)

There is no requirement that each compound within claim be equally useful for each contemplated application.

3. Specification — Sufficiency of disclosure (§62.7)

Compliance with 35 USC 112 must be adjudged from perspective that claims are addressed to person of average skill in particular art, who would not choose combination of circumstances that would render claimed composition or method inoperative.

Particular Patents — Clavulanic acid

Cole, Howarth, and Reading, Esters of Clavulanic Acid, rejection of Claims 1-445 reversed.

Appeal from Art Unit 122.

Application for patent of Martin Cole, Thomas T. Howarth, and Christopher Reading, Application Serial No. 726,224, filed Sept. 24, 1976, division of application, Serial No. 569,007, filed Apr. 17, 1975. From decision rejecting Claims 1-445, applicants appeal (Appeal No. 490-47). Reversed.

Albert L. Jacobs, Jr., New York, N.Y., for applicants.

Before Sturtevant and Milestone, Examiners-in-Chief, and French, Acting Examiner-in-Chief.

Sturtevant, Examiner-in-Chief.

This is an appeal from the final rejection of all claims in the application. Claim 445, the last claim in the case, was not included in Appellants' Notice of Appeal. However, both the Examiner and counsel have treated it as included and we have done so as well.

Claims 36-38, 83 and 120 are reproduced here to illustrate the subject matter:

36. A B-lactamase inhibitory ester of clavulanic acid.

37. A non-toxic hydrolyzable ester of clavulanic acid.

38. An ester of clavulanic acid capable of being converted to clavulanic acid or a salt thereof by hydrolysis or hydrogenolysis.

83. A pharmaceutical composition useful for treating bacterial infections in humans and animals which comprises an antibacterially effective amount of a pharmaceutically acceptable clavulanic acid ester which is hydrolyzable in vivo, in combination with a pharmaceutically acceptable carrier.

120. A method of treating bacterial infections in humans and animals which comprises administering to a human or animal in need thereof an antibacterially effective amount of a pharmaceutical composition which comprises an antibacterially effective amount of a pharmaceutically acceptable clavulanic acid ester which is hydrolyzable in vivo, in combination with a pharmaceutically acceptable carrier.

There is no art relied on. The only issue before us is whether or not all the claims comply with the requirements of 35 USC 112, paragraphs one and two. The Examiner lists eight points in support of his rejection, but not one of these points specifies claims 40-42, 44, 45, 55-58, 60 or 62-66. Despite the Examiner's omissions we have considered each of the claims on appeal vis-a-vis each of the points discussed in the Examiner's Answer. The eight points appear in the Answer (Paper No. 29) at pages 2-9 and we shall not recite them here.

[1] After careful review of the entire record we find no merit in any of the Examiner's contentions and we therefore reverse his decision. With regard to his first point, there is nothing in the statute (35 USC 112) prohibiting minor overlap of claims within the four corners of the same application. With regard to the fourth point we find the disclosure especially at page 11 fully sufficient to support compounds with an ester moiety of more than 16 carbons, even though they may not be preferred. As to the fifth point, we must totally disagree with the Examiner's position. We consider hydrolysis and hydrogenolysis, in the context of the claimed invention here, very well recognized techniques. As to the sixth and seventh points, we are in full agreement with Appellants' counter-argument as set forth in their Reply Brief (Paper No. 31) at the paragraph bridging pages 2-3.

As to the Examiner's point No. 2, the definition of the moiety NR^2R^3 in claim 39 is sufficiently clear, in context, so that the person of merely average skill in this art will not be led astray as theorized by the Examiner. We suggest that this entire issue might have been very simply resolved by omitting the phrase "wherein R^2 and R^3 are as above defined" at lines 5-4 from the end of claim 39. Indeed, it is suggested that such an amendment would be desirable even now.

Respecting the Examiner's third point, i.e. support for claims 311 through 444, we agree with Appellants that these claims are sufficiently supported in the disclosure at page 12. In addition we call attention to original claim 35, which must of course be considered as part of the original disclosure. Appeal claim 445 is substantially the same as that original claim and claims 311-355 depend directly thereon. The remaining claims of this series depend either on composition claim 67 or method claim 103, both of which also define substantially the same Markush group of esters as original claim 35.

[2] Finally, we have difficulty following the Examiner's reason in support of his eighth contention. The passage at page 105 of the specification, on which the Examiner relies to support his doubts of utility, is clearly insufficient. We know of no statutory or case law requiring each and every compound within a claim to be equally useful for each and every contemplated application. As pointed out by Appellants, the results presented at page 105 of the disclosure merely indicate that two of Appellants' claimed esters failed to inhibit the growth of one pathogen at the concentration. At page 90 of the specification results are given showing "broad spectrum activity" of one of these two esters. At page 106 antibacterial activity is clearly demonstrated for the other.

[3] With respect to all eight of the bases for the Examiner's rejection we direct the Examiner's attention to the following: In re Smith et al., 481 F.2d 910, 178 USPQ 620 (CCPA 1973) and In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973). Claims are addressed to the person of average skill in the particular art. Compliance with 112 must be adjudged from that perspective, not in a vacuum. It is always possible to theorize some

combination of circumstances which would render a claimed composition or method inoperative, but the art-skilled would assuredly not choose such a combination. See also In re Geerdes, 491 F.2d 1260, 180 USPQ 789 (CCPA 1974).

REVERSED.

Patent and Trademark Office
Trademark Trial and Appeal Board

Alpha Industries, Inc.
v. Alpha Microsystems

Decided Jan. 23, 1984

TRADEMARKS

1. Evidence — Judicial notice (§67.335)

Opposition — Consideration of marks of third party (§67.573)

TTAB will not take judicial notice of third-party applications and, in absence of evidence of actual use of third-party registered marks, such registrations are entitled to little weight.

Trademark opposition No. 64,340, by Alpha Industries, Inc., against Alpha Microsystems, applications, Serial Nos. 240,497, filed No. 26, 1979, and 242,157, filed Dec. 10, 1979. On applicant's request for reconsideration. Request denied.

See also 220 USPQ 67.

Charles Heiken, Waltham, Mass., for Alpha Industries, Inc.

Blakely, Sokoloff, Taylor & Zafman, Beverly Hills, Calif., for Alpha Microsystems.

Before Allen, Frugé, and Simms, Members.

Simms, Member.

Applicant has filed a request for reconsideration of the decision issued September 1, 1983, sustaining the opposition and refusing registration to applicant. Opposer has filed a brief in opposition to the request for reconsideration.

Among other things, applicant argues that the Board improperly found prior use by opposer of the mark ALPHA when any such rights which may have existed in opposer were abandoned since 1974. The mark ALPHA appeared on some of opposer's microwave products (semiconductors or diodes) (Andrew Kariotis dep., 46; opposer's exhibit 5, Section F). The word ALPHA also appeared prominently in some of opposer's advertisements (opposer's exhibit 9). Opposer's testimony also reveals reasons (the minute size of microwave components and customer and government specification) why no marks may have appeared on some of opposer's products (Andrew Kariotis dep., 45, 49, 53, 68). In any event, the name ALPHA has appeared and continues to appear prominently as part of opposer's trade name on or in connection with the promotion and sale of opposer's microwave parts, and purchasers over the years have variously referred to opposer as Alpha, Alpha Microwave and Alpha Industries (Andrew Kariotis dep., 64-65, 68-69, 112).

[1] In its request, applicant has disputed the Board's treatment of the numerous copies of third-party registrations relied upon by applicant. It appears that applicant is requesting the Board to take judicial notice of the statements made in each of the underlying third-party applications that the registered marks had been in use in commerce and, with respect to the registrations which bear evidence of the filing of an affidavit under Section 15 of the Act, the verified statements of the continued use of those marks residing in those registration files. The Boad will not take judicial notice of such documents and, in the absence of evidence of actual use of the third-party registered marks, the Board believes that the registrations are entitled to little weight.

Applicant's arguments concerning the sophistication of the purchasers and the lack of evidence of actual confusion have been treated in the Board's opinion. Finally, we disagree that the Board "misallocated the burden of proof." We believe that, by a preponderance of the evidence, opposer has established its priority and the likelihood of confusion.

Accordingly, applicant's request for reconsideration is denied.

Court of Appeals, Seventh Circuit

American Can Company v. Mansukhani et al.

No. 83-2553

Decided July 30, 1984. As amended Aug. 10, 1984

UNFAIR COMPETITION

1. Injunction — Preliminary injunction (§40.5)

Federal district that could have issued ex parte order directing accused trade secret misappropriator to be prepared in immediate hearing to show cause why order, permitting sampling of accused's goods and disclosure of documents, should not be entered, abused its discretion by issuing ex parte temporary restraining order authorizing trade secret owner's employees, with assistance of U.S. Marshalls, to enter accused's premises to take samples of its products and allow for copying its documents.

2. Injunction — Unfair competition (§40.9)

Injunctive orders based on standard of functional or practical similarity between trade secret owner's inks and accused misappropriator's, and adding up to permanent injunction against selling inks that are "compositionally similar" to trade secret owner's and that can be "attributed principally" to use of trade secrets, reflect standard too vague for case involving trade secrets whose scope was narrowly confined by public information and by accused misappropriator's own knowledge and experience.

Appeal from District Court for the Eastern District of Wisconsin, Warren, J.

Action by American Can Company, against Ishwar Mansukhani, doing business as Brand Associates, and Ruth Brand, doing business as Brand Associates, and Brand M, Inc., for breach of confidential relationship and unauthorized use or disclosure of trade secrets. From order granting preliminary injunction, defendants appeal. Reversed and remanded.

See also 216 USPQ 1094 and 220 USPQ 167.

Andrew O. Riteris, and Michael, Best & Friedrich, both of Milwaukee, Wis., for appellants.

Douglas W. Wyatt, and Wyatt, Gerber, Shoup, Scobey & Badie, both of New York, N.Y., for appellee.

Before Wood, Cudahy, and Flaum, Circuit Judges.

Cudahy, Circuit Judge.

This is an appeal from the district court's preliminary injunction enjoining defendants from taking actions which might constitute misappropriation of plaintiff's trade secrets. The appeal presents several important procedural issues involving the use of ex parte temporary restraining orders in trade secret cases. The appeal also involves the scope and necessary precision of injunctive relief in trade secret cases. At the heart of the case is the problem that courts face in framing orders to prevent defendants from competing unfairly by using another's trade secrets while still permitting defendants to compete fairly using public information and their own talents and experience.

I

Facts

Plaintiff-appellee American Can Company ("American Can") develops, manufactures and sells commercial jet inks. Commercial jet inks are sprayed onto a printing surface without direct contact, and they are therefore useful for printing on delicate surfaces or other surfaces for which contact printing is unsuitable. For example, some of the commercial jet inks involved in this case are used to print date codes on aluminum beer cans or to print on plastic antifreeze jugs.

Defendants-appellants are Ishwar Mansukhani, his wife, Ruth Brand, and their businesses, Brand Associates and Brand M, Inc. Mansukhani is an experienced ink chemist, and his wife is also a physical chemist, although she had no experience with inks until she and her husband started their businesses in late 1980.

The relationship between plaintiff and defendants goes back to August 1976. At that time, American Can had a wholly owned subsidiary called M & T Chemicals, Inc. ("M & T"), which was engaged in the commercial jet ink business. M & T hired Mansukhani as a chemist; at that time, he was experienced in ink chemistry but had had no experience with jet inks. He signed an agreement with M & T promising not to use its

greater showing is needed beyond uncorroborated statement that invention was made.

3. Title — Government owned (§150.11)

Employee who spent, and was paid for, 20 hours of government time in making invention, and who used government facilities to test invention, has not overcome presumption to which Army is entitled under paragraph 1(c) of Executive Order 10096, even though employee spent 20 hours of his own time in making invention.

Appeal by Dr. James E. Schroeder from determination by Army that government shall obtain entire title in invention. Affirmed.

James E. Schroeder, San Antonio, Tex., pro se.

John H. Raubitschek, for Department of the Army.

Peterson, Deputy Commissioner.

DECISION ON APPEAL

This appeal is by Dr. James E. Schroeder (Schroeder) under 37 CFR 100.7 from a determination of the Department of the Army (Army) that the Government shall obtain the entire right, title, and interest in an invention made by Schroeder. Schroeder contends that he is entitled to title subject to a license to the Government under Paragraph 1(b) of Executive Order 10096, as amended.

For the reasons hereinafter given, the Army's determination is *affirmed*.

Background

According to the record, Schroeder believes he first thought of the "invention" in January of 1982. In early February of 1982, after Schroeder had used 20 hours of his own time and 20 hours of Government time to "test" the invention, he demonstrated the invention to his supervisor. The "invention" relates to a light pen marksmanship trainer. According to the invention, a light pen attached to a rifle permits the rifle to be used for target practice in conjunction with a television screen. Thus, a rifle modified with a light pen may be used to practice target shooting on a television screen projecting images of actual targets.

[1] Schroeder's job description is such that the Army is entitled to a presumption under paragraph 1(c) of Executive Order 10096, as amended. This is so because Schroeder concedes he was hired to conduct or perform research or development work. Schroeder was hired by the Army as a research psychologist. While it could be argued that the invention was not directly related to his duties as a research psychologist, the record demonstrates — as indicated above — that Schroeder spent 50% (20 hours) of the time needed to make the invention on Government time and using Government owned computers. Prior to the use of Government time and facilities, Schroeder spent 20 hours of his own time working on the invention.

In February of 1982 Schroeder demonstrated a model of the invention to his supervisor. Upon seeing the demonstration, the supervisor authorized and encouraged Schroeder to continue to develop the invention. Schroeder spent additional Government time working on the invention. A patent application was filed by the Army. The application eventually issued as a patent (U.S. Patent No. 4,583,950, issued April 22, 1986). The patent discloses and claims an apparatus which is different from the model Schroeder demonstrated to his supervisor. Schroeder claims that the differences between the model he demonstrated to his supervisor and the apparatus claimed in the patent are *de minimus* and that he had explained to his supervisor at the demonstration how the model demonstrated could be modified to perform as a useful target marksmanship trainer for the Army.

By way of example, according to Schroeder's oral statement at a hearing held in this matter, the model demonstrated to the supervisor would function as a trainer up to a maximum of three feet from the television screen. The patent claims a device which can be used 4–20 feet from the screen. Schroeder explained to his supervisor at the demonstration that a lens in the model would have to be changed so that the model could be used at greater distances from the television screen. Another difference between the claimed subject matter of the patent and the model demonstrated to the supervisor relates to the manner in which the target was shown on the television screen. The claims call for the use of a videodisc player whereas computer software was used to create the target on the model demonstrated to the supervisor.

Schroeder did not record his idea in writing in January of 1982. Likewise, there is no contemporaneous written description of the demonstration to the supervisor. However, written statements by the supervisor made sometime after the demonstration fully corroborate Schroeder's description of the demonstration.

Issues

When was the invention "made" within the meaning of Paragraph 1(a) of Executive Order 10096, as amended?

Has Schroeder overcome the presumption of Paragraph 1(c) of Executive Order 10096, as amended?

Discussion

Schroeder contends that he "made" the invention in January of 1982 — prior to the time he used any Government time or facilities to test the invention. To the extent that Schroeder relies on any activity prior to the demonstration to his supervisor in early February of 1982, Schroeder's contention is not corroborated. Nor is there any written description by Schroeder or any other individual of the invention prior to the demonstration.

[2] The record is vague as to the precise nature of the "idea" Schroeder possessed in January of 1982. While the precise time an invention is "made" within the meaning of Paragraph 1(a) of the Executive Order must be decided on a case-by-case basis, under the facts of this case Schroeder has not appropriately demonstrated that he "made" the invention in January of 1982. Something more is needed beyond an uncorroborated statement that an invention was made in a case where there is no contemporaneous description of the invention.

Schroeder's demonstration to his supervisor is corroborated by the supervisor. There was no written description of the demonstration at the time it was made. However, Schroeder's supervisor in documents written sometime after the demonstration, fully corroborates the nature of Schroeder's demonstration and statements made by Schroeder at the demonstration as to what needed to be changed on the demonstrated prototype to make a useful target marksmanship trainer for the Army. By that time, however, Schroeder had used 20 hours of Government time and Government facilities to "make" the invention. On the record in this appeal, it will be assumed that Schroeder "made" the invention upon conclusion of the demonstration to, and discussion of the necessary changes with, his supervisor.

[3] Schroeder has not overcome the presumption to which the Army is entitled under Paragraph 1(c) of the Executive Order. It is true that Schroeder spent 20 hours of his own time in making the invention. However, it is also true that Schroeder spent (and was paid for) 20 hours of Government time in making the invention. Schroeder also used Government facilities to test the invention. It would be curious indeed if a Government employee could decide on his own to use Government time and facilities to test an invention while at the same time contend that he is entitled to title subject to a license to the Government. Compare *Houghton v. United States*, 23 F.2d 386, 390 (4th Cir.), *cert. denied*, 277 U.S. 592 (1928); *In re Phillips*, 230 USPQ 350, 352 (Comm'r. Pat. 1986). Under the circumstances of this case, it cannot be said that the Government's contribution to the invention (in time and facilities) is insufficient equitably to justify a requirement of an assignment to the Government. See Paragraph 1(b) of Executive Order 10096, as amended.

Decision

The determination of the Army that the Government is entitled to an assignment of all right, title, and interest in and to the above-identified invention is affirmed.

Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex Parte Hozumi

Appeal No. 559-94

Decided June 26, 1984

Released May 27, 1987

PATENTS

1. Patent construction — Claims — In general (§125.1301)

Finding that there exists substantial structural feature of class of compounds claimed disclosed as being essential to at least one disclosed utility, e.g., antimycotic activity, supports reversal of final rejection based on alleged improper Markush claims.

Particular Patents — Ethylene Glycol

Serial No. 257,771, Hozumi, Nomura, and Yoshioka, Ethylene Glycol Derivatives, rejection of Claims 1-6, reversed.

Application for patent of Motoo Hozumi, Hiroaki Nomura, and Yoshio Yoshioka, Serial No. 257,771, filed April 27, 1981, for Ethylene Glycol Derivatives. From rejection of Claims 1-6, applicants appeal. Reversed.

Harold C. Wegner and Wegner & Bretschneider, both of Washington, D.C., for applicants.

Before Serota, Katz, Goldstein, Lovell, and Steiner, Examiners-in-Chief.

Goldstein, Examiner-in-Chief.

This appeal is from the examiner's final rejection of claims 1 to 6. Claims 7, 9 and 12 have been withdrawn from further consideration under 37 C.F.R. 1.142(b). Claims 8, 10 and 11 have been indicated as being allowable if rewritten in independent form.

A copy of illustrative claim 1 is appended to this opinion. There are no references relied on by the examiner on appeal. Claims 1 to 6 have been finally rejected as being improper Markush claims. We shall not affirm this rejection.

The judicially created rejection of claims for "improper Markush grouping" has most recently been discussed by the Court of Customs and Patent Appeals (the predecessor to our present reviewing court, the Court of Appeals for the Federal Circuit) in the case of In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980), relied on by the examiner. The opinion in that case fairly thoroughly reviewed the history of this type of rejection and set forth, at least implicitly, some guidelines for determining whether or not a Markush group is proper. Broadly, the determinative factor was held to be whether there existed "unity of invention" or whether the claims were drawn to a collection of "unrelated inventions." Specifically, the claims in that case were drawn to a class of compounds all of which were both disclosed and claimed as being "useful as dyestuffs." All of them were also both disclosed and claimed as being "coumarin compounds." Thus, all of the claims had in common a functional utility related to a substantial, structural feature disclosed as being essential to that utility.

[1] The court was careful to point out that cases of this type are decided on their facts on a case-by-case basis. When we examine the facts in this case, we find that, as was the case in Harnisch, there is a substantial structural feature of the class of compounds claimed disclosed as being essential to at least one disclosed utility, e.g., antimycotic activity. As can be seen from the copy of claim 1 appended to this opinion, the compounds claimed are phosphoric acid diesters in which one esterifing moiety is derived from a poly(ethylene glycol) monoether and the other is derived from a beta-aminoethanol.[1] The molecular weight, i.e., the number of repeating oxyethylene units in the poly(ethylene glycol) ether moiety, can vary over a fairly broad range. The etherifying group can also vary in both molecular size and substitution. Possibly the greatest degree of variation occurs among the permitted substituents on the nitrogen atom of the aminoethanol moiety. The class recited is extremely broad. However, in view of the relatively large proportion of the structure of the compounds in the claimed class which is common to the entire class, we find that the breadth represented by the three above discussed variables does not derogate from the unity of invention in this case.

We wish to reiterate that cases of this type must be considered on a case-by-case basis and that application of the guidelines set forth in Harnisch to different facts could result in a different outcome.

Claims 1 to 6 have been finally rejected under the first paragraph of 35 U.S.C. 112 as being based on a non-enabling disclosure. The examiner has catalogued the numerous variations possible within that portion of appellants' structural formula presented by R[1], i.e., the glycol ether moiety, but has not provided any specific reasons to believe that such variations would create any difficulty for one of ordinary skill in the art to prepare the relevant compound using the general synthetic procedures disclosed at pages 3 to 6 and illustrated in the working examples. Thus, there is no evident basis for the examiner's holding of lack of enabling disclosure.

Although it is not perfectly clear, it appears that the examiner's rejection under 35 U.S.C. 112 is also based on an asserted lack of enablement with respect to the utilization of the entire genus disclosed in the antitumor utility disclosed. However, several other utilities are disclosed, and it is not necessary that all of the compounds claimed be useful for every utility disclosed in an application.

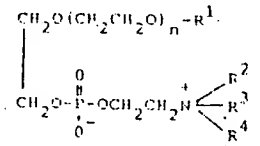
The decision of the examiner is reversed.

REVERSED

[1] In the claim, the compounds are represented as internal phosphate salts wherein the nitrogen of the aminoethanol moiety is part of an ammonium group. However, for simplicity of description, we have described the structure as though it were the one represented as Formula I' at page 2 of the specification.

APPENDIX

1. A compound of the formula:



wherein n is an integer of 1 to 15;

R^1 is C_{6-26} alkyl, C_{6-26} alkenyl or C_{6-26} alkynyl, each of said groups being unsubstituted or substituted by hydroxyl, mercapto, amino, oxo, carbamoyl, carboxyl, halogen, C_{3-7} cycloalkyl or phenyl; and R^2, R^3 and R^4 are independently hydrogen or C_{1-5} alkyl, or

represents cyclic ammonio selected from the group consisting of pyridinio, oxazolio, thiazolio, pyridazinio, quinolinio, isoquinolinio, N-C_{1-4} alkylmorpholinio and N-C_{1-4} alkylpiperazinio, each of said groups being unsubstituted or substituted by C_{1-4} alkyl, hydroxyl, hydroxyethyl, aminoethyl, amino, carbamoyl or ureido,

or a pharmaceutically acceptable salt thereof.

District Court, N.D. California

Ford Motor Co. v. Kuan Tong Industrial Co.

No. C-86-20775 SW

Decided April 16, 1987

TRADEMARKS AND UNFAIR COMPETITION

1. Trademark Counterfeiting Act — Liability (§380.01)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Contempt, sanctions (§410.49)

REMEDIES

Monetary remedies — Attorney's fees; costs — Trademark/unfair competition (§510.0907)

Defendants' sale of counterfeit automotive accessories, in violation of injunction issued pursuant to Trademark Counterfeiting Act, 18 USC 2320, warrants award to trademark owner of treble damages, based on trademark owner's lost profits, as well as award of costs and reasonable attorney's fees incurred in connection with contempt action.

Action by Ford Motor Company against Kuan Tong Industrial Co. Ltd., Powering Imports Inc., C&H Imports Inc., Simon Huang, Everen Industrial Company, and Chiao Y. Huang, for trademark infringement and counterfeiting, unfair competition, and racketeering. On plaintiff's motion for imposition of sanctions for contempt of preliminary injunction. Sanctions imposed.

David C. Hilliard, Charles R. Mandly, Jr., Debra J. Linn, and Pattishall, McAuliffe & Hofstetter, all of Chicago, Ill.; Harlan M. Richter, Neil D. Greenstein, and Pillsbury, Madison & Sutro, all of San Francisco, Calif.; and Clifford L. Sadler, Dearborn, Mich., for plaintiff.

Paul David Marotta, Jan Adam Greben, and Remer, Dunaway & Schachter, all of San Francisco, for defendants.

Williams, District Judge.

This matter having been heard on March 4, 1987 to determine appropriate sanction for the acts of contempt committed by defendants Powering Imports, Inc., C&H Imports, Inc., Simon Huang and Chiao Y. Huang, the Court makes the following findings of fact and conclusions of law in accordance with Rule 52 of the Federal Rules of Civil Procedure.

I. *FINDINGS OF FACT.*

1. On October 30, 1986, Ford filed this action for trademark infringement and counterfeiting, unfair competition and racketeering. On that date, in accordance with 15 U.S.C. section 1116(d), the Court issued the Ex Parte Temporary Restraining Order and Order to Permit Seizure. The seizure order was executed by the United States Marshal and large quantities of counterfeit and spurious Ford automotive accessories, namely, wheel covers, wheel cover emblems and decals, were seized.

In relevant part, the temporary restraining order enjoined defendants Powering Imports, Inc., C&H Imports, Inc., Simon

parent cubes that comprise the composite cube of each puzzle and that it does not extend to an analysis of the differences in the means of engagement." *Id.* at 664–65, 4 USPQ2d at 1315. Based on its assumption that this court in *Moleculon II* considered the engaging mechanism in the 2×2×2 cube to be irrelevant to a literal infringement finding, the district court concluded that the 3×3×3 and 4×4×4 cubes' engaging mechanisms should similarly not be considered in determining infringement under the doctrine of equivalents. *Id.* at 665, 4 USPQ2d at 1315–16. CBS urges that that assumption is erroneous, and we agree. Accordingly, Moleculon's lack of proof that its claim limitations directed to "engaging eight cube pieces as a composite cube" and "rotating . . . four cubes" were present by equivalency in a 26 or 56 piece puzzle [1] is fatal to its infringement claim.

In *Moleculon I* the claims at issue read literally on the method of restoring CBS's 2×2×2 puzzle. CBS, to escape this literal infringement in *Moleculon I*, would have had to prove that its different method of engaging eight cubes was a method step "so far changed in principle . . . that it performs the same or a similar function in a substantially different way." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 [85 USPQ 328, 330] (1950); *see also Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 568 (1898); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1117 n.11, 227 USPQ 577, 582–83 n.11, (Fed. Cir. 1985) (in banc). Because CBS did not raise the reverse doctrine of equivalents issue on appeal, that issue was not before this court in *Moleculon II*. We, accordingly, in upholding the district court's literal infringement finding, did not, and could not, consider that defense. However, the lack of consideration of the issue did not, and could not, erase the "engaging/rotating" limitations from the claims at issue. Consequently in *Moleculon III*, Moleculon, not CBS, bore the burden of proving that the steps of engaging 26 cube pieces and rotating eight or nine cubes, or engaging 56 cube pieces and rotating twelve or sixteen cubes are equivalent to the claimed method steps of "engaging eight cube pieces as a composite cube" and "rotating . . . four." *See* '201 patent, claim 3.

Moleculon failed to carry its burden to establish infringement under the doctrine of equivalents. Moleculon offered no evidence that, when the method of engagement and its effects on the play value of the puzzle are considered, equivalency existed in the steps of engaging and rotating cubes in an eight cube puzzle and the steps of engaging and rotating cubes in CBS' larger puzzles. Essentially, Moleculon merely asserted that its claims extend to rotation of sets of cubelets of a cube about three mutually perpendicular axes to first randomize and then restore the pre-existing pattern. That assertion entirely reads the number of cubelets and their corresponding engagement/rotation out of every step of the claim. Because of its contention that any number of cubelets in every device is equivalent to that in the claims, Moleculon made no attempt to prove that the change in the numbers used in the accused devices is an insubstantial change.

Conversely, CBS introduced abundant evidence of nonequivalency. Based upon this evidence, the district court found "that Rubik's means of engagement are far superior to anything conceived by [the patentee]," *Moleculon III*, 666 F.Supp. at 664 n.3, 4 USPQ2d at 1315 n.3, and "that the means developed by Rubik for engaging his 3x3x3 and 4x4x4 puzzles involved more creativity than that possessed by puzzle designers of ordinary skill in the art at the relevant time and contributed significantly to the appeal and commercial success of those puzzles." *Id.* at 664, 4 USPQ2d at 1315. Although a "partial variation in technique, an embellishment made possible by post-['201 patent] technology, does not allow the accused [method of restoring] to escape the 'web of infringement,'" *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1365, 219 USPQ 473, 483 (Fed. Cir. 1983), under the facts of this case, that web does not extend to Rubik's method of play. Although Rubik's larger puzzles entail steps of engaging and rotating cubes, no proof was offered that such steps in puzzles with 26 or 56 cubes were equivalents to the steps of engaging and rotating a puzzle with only eight cubes.

[1] Without evidence to support it, we cannot accept Moleculon's theory of infringement that allows the "engaging/rotating" limitations of the claim to be always met through equivalency, no matter how large the puzzles or how they are made workable. The similarities of the respective methods are superficial at best, and Moleculon presented no evidence that the accused devices are solved by a method which achieves substantially the same results in substantially the same way as the claimed method.

Having no evidence before it on which to base a finding of equivalence, the district court's finding of direct infringement by the puzzle user was clearly erroneous. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281, 6 USPQ2d 1277, 1282 (Fed. Cir. 1988). In the absence of direct infringement, CBS cannot be held liable for inducing infringement under section 271(b). *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687, 231 USPQ 474, 477 (Fed. Cir. 1986).

CONCLUSION

We hold that the district court was clearly erroneous in holding claims 3-5 of the '201 patent infringed by the 3x3x3 and 4x4x4 puzzle users, and, therefore, CBS cannot be held liable for inducing infringement under 35 U.S.C. §271(b). The judgment, accordingly, is reversed.

COSTS

Parties are to bear their own costs.

REVERSED

[1] CBS's 3×3×3 and 4×4×4 puzzles have a carved-out center that holds the engaging mechanism resulting in cube puzzles with twenty-six and fifty-six cube pieces, respectively, rather than twenty-seven and sixty-four cubelet pieces. However, the district court held that the CBS puzzles appeared to the puzzle user as a full cube. *Moleculon III*, 666 F.Supp. at 663, 4 USPQ2d at 1314.

Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Hiyamizu

No. 650-06

Decided April 28, 1988
Released October 24, 1988

PATENTS

1. Patentability/Validity — Obviousness — Person of ordinary skill in art (§115.0902)

Level of knowledge possessed by person of ordinary skill in art is somewhere between that possessed by lay person and that possessed by expert, and such hypothetical person is no more definable by way of credentials than is hypothetical "reasonably prudent man" standard in negligence law.

2. Patentability/Validity — Obviousness — References and claims as whole (§115.0904)

Patentability/Validity — Obviousness — Combining references (§115.0905)

Test, in reviewing rejection under 35 USC 103 in which examiner has relied on teachings of several references, is whether references, viewed individually and collectively, would have suggested claimed invention to person possessing ordinary skill in art, and citing references which merely indicate that isolated elements and/or features recited in claims are known is not sufficient basis for concluding that combination of claimed elements would have been obvious.

Appeal from refusal to allow claims (Martin Edlow, primary examiner).

Application for patent filed July 27, 1981, serial no. 286,863, for high electron mobility single heterojunction semiconductor devices and methods for production thereof, by Satoshi Hiyamizu and Toshio Fujii. From decision of examiner refusing to allow claims, applicants appeal. Reversed.

John P. Moran, of Staas & Halsey, Washington, D.C., for appellants.

Before Henon, Rubinson, and Hairston, examiners-in-chief.

Henon, examiner-in-chief.

This appeal is from the refusal of the examiner to allow claims 1 and 5 through 13, which constitute all the claims remaining in the application.

The invention relates to improved structure for high electron mobility heterojunction semiconductor devices. Claim 1 is considered to be representative and reads as follows:

1. A high electron mobility heterojunction semiconductor device comprising:
a semi-insulating GaAs substrate;
an undoped AlGaAs layer grown on the semi insulating GaAs substrate;
a GaAs layer grown on said undoped AlGaAs layer, said GaAs layer having a low N-type impurity concentration;
a N-type AlGaAs layer grown on said GaAs layer, and defining a heterojunction between said GaAs layer and said N-type AlGaAs layer;
at least one gate electrode formed on said N-type AlGaAs layer; and
a pair of source and drain electrodes arranged flanking said at least one gate electrode.

The references relied on by the examiner are:

Mills et al. (Mills)	4,155,784	May 22, 1979
Dingle et al. (Dingle)	4,194,935	Mar. 25, 1980
Japan (Mitsubishi)	54-12261	Jan. 29, 1979

Mimura et al. (Mimura), *Japanese Journal of Applied Physics*, Vol. 19, No. 5 (May 1980), pp. 1225–1227.

All the claims in issue stand rejected as being directed to obvious subject matter within the meaning of 35 U.S.C. 103. As evidence of obviousness, the examiner relies on the teachings of Mimura considered with Dingle, Mills and Mitsubishi. As stated in the final rejection of December 31, 1984 (paper no. 23) the apparent position of the examiner is that if the person of ordinary skill in the pertinent art were confronted with a chromium diffusion problem in a conventional high electron mobility transistor of the nature disclosed by Mimura, such an artisan would look to the teachings of Mills or Mitsubishi for a solution to the problem and would have found it obvious to include a "buffer layer" between the Mimura substrate and the undoped GaAs layer and that the artisan would have further found it obvious that the "buffer layer" may comprise both undoped GaAs or GaAlAs layers. As to the additional requirements found in dependent claims 6 through 11, the examiner relies on the teachings of Dingle.

Rather than reiterate the extensive arguments by appellants and the examiner, reference is made to the several briefs, answer and final rejection for the respective details thereof.

OPINION

Preliminarily we note that although the Figueroa patent (4,346,394) has been cited and discussed in both the final rejection and answer, it has not been included in the statement of the rejection. Accordingly, we have not considered the teachings of Figueroa in forming our decision. Note *In re Hoch*, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970).

[1] As an additional preliminary matter, we disagree with the examiner's assertion (answer page 5) that by definition "one of normal (sic, ordinary) skill in the art" is an engineer or scientist of the doctorate level working at least 40 hours per week in semiconductor research or development, as evidenced by the publication attached to appellant's principal brief. The statutory "person having ordinary skill in the art" created by Congress to provide a standard of patentability is a hypothetical person presumedly possessing knowledge in the field to which the claimed "subject matter pertains," wherein the level of said knowledge resides somewhere between that possessed by the layman and that possessed by the expert. Note *Standard Oil Company v. American Cyanamid Co.*, 774 F.2d 448, 227 USPQ 293 (Fed. Cir. 1985); and *Kimberly-Clark Co. v. Johnson and Johnson*, 745 F.2d 1437, 223 USPQ 603 (Fed. Cir. 1984). It is our view that such a hypothetical person is no more definable by way of credentials than is the hypothetical "reasonably prudent man" standard found in laws pertaining to negligence. As to the publication relied on by the examiner as evidence in support of his definition, we find that the publication fails to support said definition. That is to say, the publication fails to indicate how many hours per week the authors work, and although each of the authors has apparently earned a doctorate degree, such would merely indicate to us that the authors are highly skilled and, perhaps, experts. In summary, although the hypothetical "person having ordinary skill in the art" to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art, we disagree that the evidence in this application supports the conclusion that such a hypothetical person would require a doctorate or equivalent knowledge in science or engineering.

[2] Turning to a consideration of the rejection of the claims in issue as being directed to obvious subject matter under 35 U.S.C. 103, we find from a careful review of the record in this application that the rejection cannot be sustained. We reach such a conclusion substantially for the reasons presented by appellants in their briefs and our additional comments below.

Under 35 U.S.C. 103 where the examiner has relied on the teachings of several references, the test is whether or not the references viewed individually and collectively would have suggested the claimed invention to the person possessing ordinary skill in the art. Note *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). It is to be noted, however, that citing references which merely indicate that isolated elements and/or features recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. That is to say, there should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention. Note *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986). Furthermore, it is well settled that where the claimed invention solves a problem, the discovery of the source of the problem and its solution are considered to be part of the "invention as a whole" under 35 U.S.C. 103. Note *In re Kaslow, supra; In re Nomiya*, 509 F.2d 566, 184 USPQ 607 (CCPA 1975); and *In re Sponnoble*, 405 F.2d 578, 160 USPQ 237 (CCPA 1979).

Reviewing the prior art relied on by the examiner, we initially note that none of the references teaches or suggests the problem and its possible causes as identified by appellants beginning at the last paragraph of page 4 of the specification. However, even if we presume for the sake of argument that the admissions found in the paragraph bridging pages 2 and 3 of appellants' disclosure coupled with the discussion found in Mills and Dingle pertaining to the effects of impurity migration would have suggested the problem noted by the examiner at page 3 of his final rejection and would have served as motivation to look to the prior art for a solution to the problem, we are not convinced that the collective teachings of the references would have suggested appellants' claimed solution. For example, Mimura merely teaches a structure similar to that which is admitted by appellants to be known in their specification and the reference includes no teachings or suggestions pertaining to the problem or its solution as identified by appellants.

Mills teaches the inclusion of a gallium arsenide buffer layer between the substrate and the active layer so as to prevent migration of the substrate dopant into the active layer. However, both Mimura and the admitted prior art structure already include such a buffer layer. As to the teachings of Mitsubishi, we do not consider the reference to teach the interchangeability of the claimed ternary material for the binary material taught by Mills, as seemingly urged by the examiner at page 7 of the answer. The functions for the respective layers as taught by the references are different. That is to say, Mills teaches the inclusion of the binary buffer layer for the purpose of preventing the migration of chromium to the active layer, whereas, Mitsubishi teaches the inclusion of the ternary layer for the purpose of, *inter alia*, forming the heterojunction at the boundary between the operating layer and the buffer layer. Moreover, the claim requires defining the heterojunction between the upper GaAs layer and the N-type AlGaAs layer. In light of the above, it would appear to us that it would not have been obvious to modify Mimura in the manner urged by the examiner without using appellants' claims as a guide. It is to be noted that simplicity and hindsight are not proper criteria for resolving the issue of obviousness; note *In re Horn*, 203 USPQ 969 (CCPA 1979). As to the teachings of Dingle which, in some respects, are far more pertinent to the problem and its solution as disclosed by appellants, we note that the solution taught by the reference, namely modulating the doping and bandgap of the multilayered structure (column 3, second full paragraph), is significantly different from the structure specified in the claims in issue. In light of the above, we are convinced that the evidence adduced by the examiner fails to support his conclusion that the claims at bar are directed to obvious subject matter within the meaning of 35 U.S.C. 103.

DECISION

The decision of the examiner rejecting claims 1 and 5 through 13 under 35 U.S.C. 103 is reversed.

REVERSED

Court of Appeals, Third Circuit

CW Communications Inc. v. International Research Services Inc.

No. 88-3331

Decided October 31, 1988
(Unpublished)

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Registration and its effects — Federal registration — Incontestability — In general (§315.0309.02)

Mark which is merely descriptive may be non-registrable, but once mark obtains incontestable status mere descriptiveness cannot be used as basis for challenging it.

2. Types of marks — Generic marks — Particular marks (§327.0605)

Mark "ComputerWorld," for newspaper directed to those interested in computers, is not generic.

3. Infringement; conflicts between marks — Likelihood of confusion — Particular marks — Marks similar (§335.0304.03)

Federal district court's finding of likelihood of confusion between "ComputerWorld," for newspaper directed to those interested in computers, and "Computer World," for retail store services, distributor-

ship services, and leasing services in field of computers, was not clearly erroneous.

Appeal from the U. S. District Court for the Western District of Pennsylvania, McCune, J.

CW Communications Inc. brought trademark infringement action against International Research Service Inc. From federal district court decision granting plaintiff's motion for injunction, defendant appeals. Affirmed.

[Editor's note: This opinion has been marked "not for publication."]

Before Sloviter and Hutchinson, circuit judges, and Gerry, chief district judge (sitting by designation).

Sloviter, J.

C.W. Communications, Inc. (CWC), the publisher of a weekly newspaper named COMPUTERWORLD directed to those interested in computers, is the owner of a trademark registration for the name "COMPUTERWORLD" for a trade newspaper. Its trademark has now become incontestable because it has been in continuous use for five consecutive years since its registration in 1968. *See* 15 U.S.C. §§1065, 1115(b) (1982). In fact, it has been publishing COMPUTERWORLD since 1967, and the circulation of COMPUTERWORLD has reached 125,000 subscriptions in the United States and 8,000 overseas. The newspaper contains approximately 150 pages per issue, and carries extensive advertising by manufacturers, sellers, and lessors of computer equipment.

Defendant-appellant International Research Service, Inc. (IRS) entered business by selling and leasing computers and parts in 1980. In 1983, it opened a retail store under the name "Computer Town," which was changed to "Computer World" in 1985. IRS has had no retail store since 1986. Instead, it markets a "Franchise Investment Guide," a seven-page brochure which advertises "Computer World" stores as featuring "a broad line of micro-computer products," app. at 35, and encourages investors to purchase "Computer World" franchises along with the protection of the trademark "Computer World," app. at 34. In 1984, IRS was granted a Trademark Registration for the name "Computer World" for "retail store services, distributorship services and leasing services in the field of computers." App. at 33.

In 1984, CWC filed suit alleging that IRS' use of the name "Computer World" in the computer field was likely to cause confusion in the trade and mislead the public into the belief that IRS' goods and services were those of CWC.

Following a nonjury trial, the district court granted CWC's motion for an injunction against IRS' use of the name "Computer World" or offer to franchise use of this name with respect to any business selling, leasing or distributing computers, hardware, software, or parts of equipment used in data processing. The court found that IRS' use of this name created a significant likelihood of confusion.

On appeal, IRS argues that the court erred in upholding CWC's trademark infringement claim against use of a mark similar to its own on goods and services other than those described in CWC's trademark registration certificate and affidavit submitted to obtain incontestable status under section 15 of the Lanham Act. 15 U.S.C. §1065 (1982). It also argues that the district court erred in rejecting its argument that CWC's service mark was not protectable because it was generic, descriptive, and lacked secondary meaning.

[1] Turning first to the latter issue, the district court held that the Supreme Court's decision in *Park 'N Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189 [224 USPQ 327] (1985), foreclosed IRS' argument regarding the "mere descriptiveness" of Appellee's mark. We agree. As the court held in that case, "[w]ith respect to incontestable marks . . . §33(b) provides that registration is *conclusive* evidence of the registrant's exclusive right to use the mark, subject to the conditions of §15 and the seven defenses enumerated in §33(b) itself. Mere descriptiveness is not recognized by either [of these sections] as the basis for challenging an incontestable mark." *Id.* at 196 [224 USPQ at 330] (emphasis in original). Although a merely descriptive mark may be nonregistrable, such challenges are foreclosed once a mark obtains incontestable status. *Id.*

IRS argues however, that COMPUTERWORLD is not merely descriptive but also generic. In *Park 'N Fly*, the Court noted that "[a]n incontestable mark that becomes generic may be canceled at any time" under the statute. *Id.* at 195 [224 USPQ at 330].

[2] "A generic term is one that refers to the genus of which the particular product is a species." *Id.* at 194 [224 USPQ at 329]. In the course of this court's exegesis on genericness in *A.J. Canfield Co. v. Honickman*, 808 F.2d 291 [1 USPQ2d 1364] (3d Cir. 1986), we explained that "[w]hether the term that identifies the product is generic . . . depends on the competitors' need to use it." *Id.* at 306 [1 USPQ2d at 1376]. Unlike the name "Consumer Electronics Monthly" for a trade magazine which the court in *CES Publishing Corp. v. St. Regis*, 531 F.2d 11 [188 USPQ 612] (2d Cir. 1975), held to be generic, it would not be difficult for other businesses in the computer field "to flourish and identify themselves" without use of "COMPUTERWORLD." *See id.* at 15 [188 USPQ at 616]. Under any of the tests for genericness discussed by us in *A.J. Canfield*, "COMPUTERWORLD" is not generic, and hence the district court did not err in rejecting IRS' challenge to the validity of CWC's trademark registration.

We consider next IRS' principal contention on appeal, i.e. that a holder of an incontestable trademark may not preclude others from using that mark on different goods or services even if the district court has found such use is likely to cause confusion. Although we held in *Natural Footwear Ltd. v. Hart, Schaffner & Marx*, 760 F.2d 1383, 1396-97 & nn.27 & 31 [225 USPQ 1104, 1112-13 & nn. 27 & 31] (3d Cir.), *cert. denied*, 474 U.S. 920 (1985), that the federal registration of a mark provides protection against use of the mark by others for the goods or services specified in the registration certificate, we also made clear that common law principles provide protection against uses beyond those specified in the certificate. Under the modern test, the question to be asked when similar trademarks are used on different but related goods or services is whether "the reasonably prudent purchaser [is] likely to be confused as to source, connection or sponsorship between the goods or services[.]" J. MacCarthy, *Trademarks and Unfair Competition* §24:1, at 161 (2d ed. 1984).

Applying the test for likelihood of confusion enunciated in *Scott Paper Co. v. Scott's Liquid Gold, Inc.*, 589 F.2d 1225, 1229 [200 USPQ 421, 425] (3d Cir. 1978), the district court found some evidence of actual confusion, marketing of both products to "people interested in the same thing," and evidence establishing "likelihood of confusion as a matter of fact." App. at 36. Appellant argues that the district court's application of the test in *Scott Paper* was erroneous because it found only five of the ten factors listed there had been met. Nothing in *Scott Paper* suggests that courts may find a likelihood of confusion only after tallying up the number of factors for and against this finding. Instead, "[e]ach case . . . must be evaluated on its own facts and circumstances." *Id.* at 1231 [200 USPQ at 426-27].

For that reason, IRS' reliance on our decision in *Family Circle, Inc. v. Family Circle Assocs., Inc.*, 332 F.2d 534 [141 USPQ 848] (3d Cir. 1964), is misplaced. Although we upheld the trial court's finding that no likelihood of confusion existed with respect to use of the mark "Family Circle" by both a magazine and a discount retail business, that cannot control the outcome here. In *Family Circle*, the trial court had evaluated the similarity of the marks and the products sold under it, the good faith of the defendants, the credibility of their testimony that they were not attempting to trade on the name or good will of the plaintiff, and "the probability that reasonably prudent consumers would be confused." *Id.* at 540 [141 USPQ at 853]. Evaluating the same factors, the trial court in this case reached the opposite result. Moreover, the court also "lack[ed] confidence in the credibility" of IRS' owner, Aslam M. Shaw, app. at 36, and did not accept his testimony that he had never heard of the newspaper COMPUTERWORLD when choosing the name for his business.

[3] The court's factual findings as to likelihood of confusion are reviewable under the clearly erroneous standard. *See American Home Prods. Corp. v. Barr Laboratories, Inc.* 834 F.2d 368, 370 [5 USPQ2d 1073, 1075] (3d Cir. 1987). We cannot denominate the findings in this case on likelihood of confusion as clearly erroneous.

For the foregoing reasons, we will affirm the judgment of the district court.

Court of Appeals, Federal Circuit

In re Laskowski

No. 88-1349

Decided April 3, 1989

PATENTS

1. Patentability/Validity — Obviousness — Combining references (§115.0905)

Applicant's band saw drive wheel employing loosely fitted tire is not obvious in view of prior patent using tightly fitted or bonded tire, and other, secondary references, since prior art does not suggest applicant's modification to primary reference or provide any reason or motivation for making such modification.

Appeal from the Patent and Trademark Office Board of Patent Appeals and Interferences.

Patent application of Donald R. Laskowski and Daniel R. Tekulve, serial no.

6. At all times during which the labels were used the firearms in the boxes marked with the labels were made under one or more Ruger U.S. patents or under a patent pending owned by Ruger.

7. All three labels were prepared on the advice of patent counsel.

8. Ruger replaced the 1978 label with the 1984 label in response to the filing of the complaint in this action, which called the inaccuracies in the label to its attention.

9. The 1984 label reads in part: "The firearm in this box *may be* manufactured under one or more of the following patents * * *" (emphasis added). This statement is accurate and not deceptive.

10. No evidence was offered to show that inaccuracies in the labels were anything more than "oversights," as William Ruger, Sr., a Ruger officer, testified. There was no evidence of intent to deceive on the part of Ruger.

11. Ruger used statements relating to patents and patent applications in its promotional material. No proof has been offered that these statements were not accurate.

CONCLUSIONS OF LAW

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a). Venue is proper pursuant to 28 U.S.C. § 1391.

2. To establish a violation of 35 U.S.C. §292(a), plaintiff must demonstrate that defendant falsely marked an unpatented item in such a way as to indicate that it was patented, with the purpose of deceiving the public. 35 U.S.C. § 292(a), *Johnson v. Textron*, 579 F. Supp. 783, 795, 222 USPQ 160, 169-170 (D.R.I. 1984).

3. Unintentional mistakes in marking products do not establish a violation of § 292. *Johnson v. Textron*, 579 F. Supp. at 795, 222 USPQ at 169-170.

4. Reliance on counsel can be a defense to the specific intent element of § 292. *Victoria-Vogue v. Valcourt, Inc.*, 148 F. Supp. 160, 171, 113 USPQ 41, 49-50 (S.D.N.Y. 1956).

5. The burden of proof of showing that defendant acted with the specific intent to deceive the public is on the plaintiff. *Brose v. Sears Roebuck & Co.*, 455 F.2d 763, 768, 172 USPQ 454, 457 (5th Cir. 1972).

[1] 6. Plaintiff has failed to offer any evidence, either direct or circumstantial, from which an inference could be drawn that defendant acted with specific intent to deceive with regard to either the box labels or the brochures and other advertising. Plaintiff has had over nine months of discovery, during which it has deposed Ruger's officers and the box manufacturers. Nonetheless, it has produced no evidence of intent, nor any evidence suggesting that evidence of intent could be produced at the time of trial. Defendant, in contrast, has offered testimony by Ruger officers that any mismarking was an "oversight," that the company relied on patent counsel to prepare the labels, and that the labels were changed when defendant was made aware of their inaccuracies. While ordinarily, intent is a question of fact to be decided by the trier of fact, *Brose v. Sears, Roebuck & Co.*, 455 F.2d at 769, 172 USPQ at 457-458 in this case no genuine issue has been raised on this point. *See id.* (affirming trial court's dismissal of §292 action at conclusion of plaintiff's case due to lack of evidence of intent).

[2] 7. The statute of limitations for an action brought under § 292 is the five year limit for civil fines or penalties which is set forth in 28 U.S.C. § 2642.

8. Plaintiff's claims based on the 1973 label, which was in use only through 1978, are time-barred.

9. The 1984 label used by defendants is not deceptive or violative of § 292 as a matter of law.

10. The plaintiff has failed to demonstrate that any violations of § 292 appeared in defendant's promotional materials.

11. There is no genuine issue of material fact and Ruger is entitled to judgment as a matter of law. Judgment shall be entered accordingly.

Court of Appeals, Federal Circuit

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., et al.

No. 84-1779

Decided October 25, 1985

PATENTS

1. Invention — Specific cases — Chemical (§51.5093)

Federal district court committed reversible error in combining teachings of prior art to reach conclusion of obviousness of claimed subject matter and process, in substituting claimed resin, of which one of ordinary skill in art would not have knowledge, into prior art patent and concluding obviousness therefrom, in failing to consider evidence going to secondary considerations, and in failing to determine whether there was nexus between proffered evidence of secondary considerations and merits of claimed invention.

Particular patents — Foundry Binders

3,409,579, Robins, Foundry Binder Compositions Comprising Benzylic Ether Resin, Polyisocyanate, and Tertiary Amine, holding of invalidity of claims 14 and 19 reversed.

3,485,797, Robins, Phenolic Resins Containing Benzylic Ether Linkages and Unsubstituted Para Positions, holding of invalidity of claims 1, 2, 7, and 10, reversed.

3,676,392, Robins, Resin Compositions, holding of invalidity of claim 17, reversed.

Appeal from Distict Court for the Eastern District of Michigan, Feikens, J.; 222 USPQ 688.

Action by Ashland Oil, Inc., against Delta Resins & Refractories, Inc., et al., for patent infringement and misappropriation of trade secrets. From judgment for defendants, plaintiff appeals. Reversed.

Bruce Tittel, and Wood, Herron & Evans, both of Cincinnati, Ohio (William G. Konold, Cincinnati, Ohio, on the brief) for appellant.

Donald E. Egan, and Cook, Wetzel & Egan, Ltd., both of Chicago, Ill., for appellees.

Before Markey, Chief Judge, and Davis and Kashiwa, Circuit Judges.

Kashiwa, Circuit Judge.

Ashland Oil, Inc. (Ashland) appeals from the judgment of the United States District Court for the Eastern District of Michigan, Southern Division, holding claims 1, 2, 7 and 10 of U.S. Patent No. 3,485,797 (the '797 patent), claims 14 and 19 of U.S. Patent No. 3,409,579 (the '579 patent), and claim 17 of U.S. Patent No. 3,676,392 (the '392 patent) invalid under 35 U.S.C. §103. We reverse and remand.

Background

Ashland is the assignee of the three patents involved in this case, which were issued to Dr. Janis Robins. These patents are directed to certain chemical products and processes finding ultimate use in the foundry industry. One method of forming metal castings in the foundry industry involves compacting sand around a pattern to form a sand mold, removing the pattern, and then pouring molten metal into the sand mold. This process often involves the use of internal sand cores around which the molten metal flows to produce various internal configurations.

A chemical binder, for example a phenolic urethane formed by reacting a phenol-formaldehyde resin with a hardener component, such as a polyisocyanate, and a curing agent, such as as teritiary amine, is mixed with the sand, causing the sand-binder mixture to harden at a predetermined rate. After the sand mold mixture has hardened, the mixture retains its shape during the pouring of the molten metal. After the metal solidifies the binder must break down to permit the sand to be readily dislodged from the casting.

An optimized sand-binder mixture should have a slow or negligible curing period after the initial mixing of the binder with the sand, i.e., the work time, followed by a period of rapid curing. During the work time, the sand-binder mixture remains flowable, due to negligible curing or hardening, to allow easy forming of the mixture to conform to the pattern. Rapid curing after the mold has been formed allows the sand-binder mixture to rapidly reach its hardened state, thus permitting initiation of molten metal pouring.

Ashland sued Delta Resins & Refractories, Inc. (Delta) [1] for infringement of claims 1, 2, 7 and 10 of the '797 patent, claims 14 and 19 of

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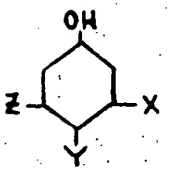
[1] The voluminous record submitted by the parties did not include a complaint listing the defendants in this case. The Joint Final Pretrial Report, paragraphs 5-8, indicates that, in addition to Delta Resins & Refractories, Inc., the named defendants are the Aristo Corporation, David Horstman, Lawrence D. Kancius and Gary Lukacek.

the '579 patent and claim 17 of the '392 patent. Claims 1, 2, and 7 of the '797 patent are directed to a process for producing a phenol-formaldehyde resin which may be used in producing a chemical binder useful in the formation sand molds. Claim 10 of the '797 patent is directed to one of the resin products derived from this process.

Claim 1 of the '797 patent is a broad process claim [2] directed to reacting a phenol and aldehyde in the presence of a catalyst and reads as follows:

1. A process for the preparation of phenol aldehyde reaction products which comprises reacting a phenol having the general formula wherein X, Y, and Z are hydrogen, hydrocarbon radicals, oxyhydrocarbon radicals or halogen, with an aldehyde having the general formula R'CHO wherein



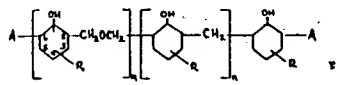
R' is hydrogen or a hydrocarbon radical of 1-8 carbon atoms at a mole ratio of aldehyde to phenol of greater than 1,

in the liquid phase under substantially anhydrous conditions with the removal of water above 100°C and

at temperatures below about 130° C in the presence of catalytic concentrations of a soluble divalent metal salt dissolved in the reaction medium.

Claim 10 of the '797 patent is directed to a phenol-formaldehyde resin (Pep resin) [3] and reads as follows:

10. The phenol formaldehyde resin having the general formula wherein R is hydrogen, hydrocarbon radical, oxyhydrocarbon radical or halogen, meta to the hydroxyl group of the phenol; m and n are numbers the sum of which is at least two and the ratio of m-to-n is greater than one; and A is a hydrogen or a methylol group, the molar ratio of said methylol group to hydrogen being at least one.[4]

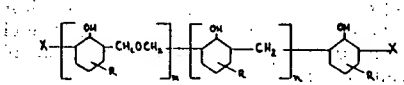


Claim 14 of the '579 patent [5] is a dependent claim [6] directed to a foundry mix which contains sand as the major constituent and up to 10% by weight, based upon the weight of the sand, of a binder composition. The binder composition comprises in admixture the Pep resin as described in claim 10 of the '797 patent, a hardener component comprising a liquid polyisocyanate containing at least two isocyanate groups and a curing agent comprising a tertiary amine.

Claim 19 of the '579 patent is a dependent claim [7] which reads as follows:

19. The process of preparing shaped foundry products which comprises:

(a) forming a foundry mix by uniformly distributing on a foundry aggregate containing sand as the major constitutuent a binding amount of up to 10% based on the weight of the aggregate of a binder composition obtained by combining [a phenolic resin having the general formula wherein R is hydrogen or a phenolic substituent meta to the hydroxyl group of the phenol, m and n are numbers the sum of which is at least 2, and the ratio of m-to-n is at least 1, and X is a hydrogen or a methylol group, the molar ratio of said methylol group-to-hydrogen being at least 1] and hardener component of claim 1, said polyisocyanate being employed in a concentration of 10 to 500% by weight of the phenolic resin;



(b) shaping the foundry mix in a mold; and

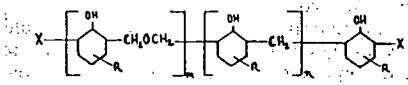
(c) contacting the shaped foundry mix with a tertiary amine until the binder is cured.

(bracketed material added, *see supra* note 7).

Claim 17 of the '392 patent [8] is a dependent claim [9] which reads as follows:

17. A foundry mix containing sand as the major constituent, and a binding amount of up to 10 percent based on the weight of sand of the resin composition [, said resin composition comprising in admixture,

a benzylic ether resin which has the general formula wherein R is hydrogen or a phenolic substitutent meta to the hydroxyl group of the phenol, m and n are numbers the sum of which is at least 2, X is an end-group from the group consisting of hydrogen and methylol, and wherein m is at least 1 and the sum of m and the number of methylol end-groups is at least two,



a hardener component comprising a liquid polyisocyanate containing at least two isocyanate groups and present in an amount equal to 10 to 500 weight percent based on the weight of the resin, and

a curing catalyst having a pK_b value in the range of about 7 to 11 and present in an amount equal to 0.01 to 10.0 weight percent based on the weight of the resin].

(bracketed material added, *see supra* note 9).

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[2] Process claim 2 further limits the reaction temperature of the process from about 110 to 120° C. Process claim 7 limits the soluble divalent metal salt to salts of lead or zinc.

[3] The district court characterized the '797 resin of claim 10 as such and we adopt this terminology. Conventional phenolic resin chemistry describes two groups of phenolic resins: resoles and novolacs. Resoles are formed by reacting a phenol with excess formaldehyde in the presence of an alkaline catalyst while novolacs are formed by reacting an excess of phenol with formaldehyde in the presence of an acidic catalyst. R. MARTIN THE CHEMISTRY OF PHENOLIC RESINS, 88 (Fig. 2) (John Wiley & Sons, Inc. 1956). The use of the process of claim 1 to form the Pep resin requires that an excess of formaldehyde be reacted with phenol in the presence of a soluble divalent metal salt catalyst. The specification of the '797 patent teaches that the salt radical of the catalyst should be that of a stronger acid. Thus, the phenolic resin formed by the process of the '797 patent, as claimed in claim 10, fails to fall squarely into either group of phenolic resins described in the prior art, resoles or novolacs.

[4] The left hand phenol depicted *supra* has been labeled so that the ortho (2, 6), meta (3, 5) and para (4) positions are identifiable. CH_2 - 0 - CH_2 identifies a benzylic ether bridge, CH_2 identifies a methylene bridge, OH is the chemical designation for a hydroxyl group, and CH_2OH is the chemical designation for a methylol group.

[5] In prior litigation between Ashland and Delta, claims 1, 13, 15, 16 and 18 of the '579 patent were invalidated for obviousness. *See Ashland Oil, Inc. v. Delta Oil Products,* 212 USPQ 508 (E.D. Wis. 1981), *rev'd in part,* 685 F.2d 175, 216 USPQ 857 (7th Cir. 1982), *cert. denied,* 103 S.Ct. 1769 (1983). None of these prior invalidated claims involved the Pep resin of claim 10 of the '797 patent.

[6] Claim 14 incorporates the binder composition of claim 6, claim 6 in turn being dependent upon claim 1, the broad binder composition claim of the '579 patent.

[7] Claim 19 has been redrafted in the format of claim 15, with the addition of the relevant portion of claim 6, to facilitate review. Claim 19 is dependent upon claim 15, and incorporates the phenolic resin of claim 6, i.e., the Pep resin of claim 10 of the '797 patent.

[8] In the prior action between Ashland and Delta, *see supra* note 5, the district court had held all claims of the '392 patent invalid for obviousness. The Seventh Circuit reversed in part, holding that only claims placed in issue, in that case claims 1 and 16, were subject to invalidation. The invalidated claims were not directed to the use of the Pep resin.

[9] Claim 17 incorporates the resin composition of claim 1, with the additional limitation of claim 7 wherein the phenolic resin component is a benzylic ether resin. The relevant portion of claim 7 has been incorporated into claim 17 to facilitate review.

District Court Proceedings

The district court noted that although the ultimate question of patent validity is a legal one, the determination of obviousness lends itself to several basic factual inquiries, to wit, the scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. The court recognized that Delta, as the party asserting patent invalidity, has the burden of proving that the claimed inventions in issue would have been obvious by clear and convincing evidence. Once Delta has established a *prima facie* case of obviousness, the burden of going forward shifts to Ashland to rebut with evidence of nonobviousness, although the burden of persuasion remains with Delta.

The court found that a person of ordinary skill in the art would have a bachelor's degree in chemistry, several years experience in phenolic and urethane chemistry, and several months exposure to the foundry art.

a. '797 Resin Claim:

The court stated that Delta relied primarily upon three prior art references to support its argument that the invention set forth in claim 10 would have been obvious: (1) U.S. Patent No. 2,079,633 (the Rothrock patent); (2) N. MEGSON, PHENOLIC RESIN CHEMISTRY (Academic Press Inc. 1958); and (3) R. MARTIN, THE CHEMISTRY OF PHENOLIC RESINS (John Wiley & Sons, Inc. 1956).

Claim 10 of the '797 patent, the court stated, requires that the sum of m and n must be at least two such that Ashland's Pep resin must have at least three rings and may have up to forty. The Pep resin contains some three ring and greater molecules, along with a substantial amount of one and two ring adducts. The court

found [10] that the process disclosed in the Rothrock patent produces claim 10 material, although having a large portion of adducts and only a small amount of three ring or greater molecules. Ashland denied that the Rothrock process produces the Pep resin of claim 10, and averred that the Rothrock resin is inferior to the Pep resin as a foundry binder because Rothrock's hydroxyl groups are modified by butyl alcohol solvents.

As to the MEGSON reference, diagram A, see Appendix, illustrates a polybenzylic ether resin within the scope of claim 10. The drawing shows phenol-formaldehyde resin molecules having an ortho-ortho orientation, connected by either bridges, and an open para position. Claim 10 requires the sum of methylene and ether bridges to be at least two, and while the molecule of the diagram does not show methylene bridges, it is still within the scope of claim 10 because it satisfies the requirement that the sum of methalene and ether bridges with its two ether bridges. Ashland's position is that MEGSON does not disclose instructions for the preparation of this polybenzylic ether resin, and further that the molecule depicted in diagram A is only a hypothetical structure postulated to be present during curing, not what is present in a room temperature reaction product.

MARTIC discloses a linear polymeric ether resin containing up to thirty-five phenol rings linked together by ether bridges in an ortho-ortho orientation. Jordan Kopac, Delta's president,[11] testified that MARTIN teaches how ether linkages are formed, and how the number of ether linkages may be increased. Further, as temperature increases, some ether linkages will break down, producing methylene linkages and formaldehyde, the formaldehyde being available to cross-link the resin. The position of Ashland was that the open para position of the Pep resin allows phenol reaction at this site, an important consideration in producing a superior binder, but MARTIN teaches a structure which is para substituted.

Based upon this prior art, the court found that while no single prior art reference rendered the Pep resin of claim 10 obvious, the references taken together would have suggested that resin. *See Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 739, 220 USPQ 845, 848–49 (Fed. Cir. 1984). Therefore, Delta had sustained its burden of proving by clear and convincing evidence that the Pep resin of claim 10 would have been obvious to one of ordinary skill in the art.

The Rothrock patent, MEGSON, and MARTIN collectively suggest the critical elements of the claimed material, i.e., a phenol-formaldehyde resin containing linear polymers which consist of phenol rings connected by ether bridges or ether and methylene bridges in an ortho-ortho orientation having an unsubstituted para position.

The court held that Ashland's evidence was insufficient to rebut Delta's clear and convincing evidence that claim 10 would have been obvious to one skilled in the art in light of the prior art, and that Ashland failed to establish that one of ordinary skill in the art would have been unable to read the prior art references and "discover" the resin claimed by Robins.

b. '797 Process Claims:

The court stated that Delta had sustained its burden of proving by clear and convincing evidence that the prior art discloses reacting phenol with formaldehyde under essentially the same conditions as the Robins patent, finding that the prior art cited by Delta would have suggested to one of ordinary skill in the mid 1960s the possibility of developing the process claimed in claims 1, 2 and 7 of the '797 patent. The Rothrock patent describes a process for manufacturing phenolformaldehyde resins, teaching a process using: (1) a formaldehyde/phenol ratio greater than 1; (2) paraformaldehyde (the anhydrous form of formaldehyde), and removal of water in some cases; a temperature range of 100–120° C; and (4) soluble metal salt catalysts, including zinc acetate.

Japanese Patent 13696/60 describes a process for producing phenol-formaldehyde initial condensates, by reaching phenol and formaldehyde: (1) under anhydrous polymerization conditions (starting with paraformaldehyde and removing water); (2) at temperatures above 100° C and as high as 120° C; and (3) using soluble metal salts as catalysts. Although the examples of the Japanese Patent teach of formaldehyde/phenol ratio less than 1, the specification teaches that a formaldehyde-/phenol ratio greater than 1 may be used.

The prior art reference of Fraser, Hall & Raum, *Preparation of 'High-Ortho' Novolak Resins*, J. App. Chem. (Dec. 1957), teaches the effectiveness of zinc and lead as catalysts to form ortho-ortho linked phenol-formaldehyde chains, and that benzylic ether bridges are formed at reaction temperatures below 140° C.

There are differences between this prior art and the '797 process claims. The Rothrock patent does not teach removal of water above 100° C and the Fraser reference does not teach the removal of water at all. Both Rothrock and the Japanese Patent use butyl alcohol as a solvent, whereas Robins discloses the use of toluene. The '797 claims in issue, however, do not mention the use of solvents. The butyl alcohol modified resin of Rothrock is not a phenolic resin. Ashland has also argued that neither the Japanese Patent nor Fraser produce compounds with more than two rings.

But, the court stated that Ashland had failed to establish that these differences, in light of Delta's proof, are great enough to render the inventions in issue non-obvious. The cited references collectively, if not individually, teach: (1) a formaldehyde/phenol ratio greater than 1; (2) anhydrous conditions; (3) a reaction temperature range of 100–120° C; and (4) soluble metal salt catalysts. The differences between the prior art and the claims in issue are insignificant because one of ordinary skill in the art could study the prior art references and come upon the '797 process claims.

For example, one of ordinary skill could read Rothrock and recognize that varying the solvent in Example 5 and removing water — as Rothrock did in Examples 1 and 7 – yields a process, which could be substantially similar to the '797 process, for preparing certain phenol-formaldehyde reaction products. Similarly, although the Japanese Patent and the Fraser reference do not produce compounds with greater than two rings, one of ordinary skill reading these pieces of prior art could apply his knowledge and develop a process for preparing a phenolic resin which could be substantially similar to the process of the '797 patent.

c. The '579 and '392 Foundry Binder Claims:

The '579 and '392 foundry binder systems consist of the Pep resin, a polyisocyanate hardener, and a tertiary amine catalyst for the '579 claims or a catalyst with a pKb value of about 7 to about 11 for the '392 claim.

Delta argued that the prior art, i.e., U.S. Patents Nos. 3,409,571 ('571 patent) and 3,398,122 ('122 patent) issued to Shepart and British Patent 1,031,909, disclosed the use of phenolic urethanes as foundry binders. Dr. Frisch, an expert witness, testified that Robins' foundry binder claims would not have been obvious to one skilled in the art. One skilled in the art would not expect polyurethanes to work as foundry binders since it was known in the field that reacting phenol with isocyanates results in a blocked phenol forming an unstable urethane which disassociates or reverts to phenol and isocyanates upon heating at temperatures of 140–150° C.

The court's examination of the prior art led it to conclude otherwise. While recognizing that the British Patent [12] was technically not prior art, it was indicative of what was known to persons of ordinary skill in the art. The patent described reacting novolac resins with highly reactive divalent materials to form a soluble product which can then be thermoset to produce a foundry binder, and such a claim is made in claim 12. The court concluded that the British Patent discloses the use of phenolic urethanes as foundry binders.

The court found the Shepard patents significant in that Shepard described a novolac phenolic resin modified with a phosphorous compound, i.e., a soluble thermoplastic. Shepard's '571 patent clearly states that thermosetting products can be produced by mixing thermoplastic products with polyisocyanates, and that such thermosetting products are useful as foundry sand binders. Based upon the foregoing, the court concluded that the use of phenolic urethanes as foundry binders was taught by the prior art.

While Ashland argued that Shepard teaches the use of a novolac resin while the '579 and '392 claims here in issue use the Pep resin, the court found this difference insufficient to warrant a finding of nonobviousness. One skilled in the art could readily sense that the Pep resin might be substituted into the Shepard patent. It was known in the prior art how ether

[10] Ashland has argued that the district court made few factual findings, that the court was merely presenting the arguments of the parties. While the format of the court's opinion lends some credence to this argument, we note that the court properly recognized that it was required to make factual determinations on the scope and content of the prior art and the differences between the prior art and the Robins patents. *See Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Thus, the court's exposition appears to be the court's shorthand method of examining the prior art and the differences between the prior art and the patents in issue. Consequently, we review these statements by the court as its factual findings.

[11] During pretrial discovery Delta had identified Dr. Raymond Wentland as its only expert witness. Dr. Wentland was not called to testify during trial. Instead, Delta chose to rely primarily on the testimony of Mr. Kopac, who although possessing the qualifications of one of ordinary skill in the art, had not been qualified to testify as an expert witness.

[12] The application on the British patent was filed in London on 5 November 1963 and published on 2 June 1966. This application was based upon a prior United States application, Serial No. 241,131, filed 30 November 1962. The application on the '797 patent was filed on 14 March 1962, the application on the '392 patent had a continuation-in-part filing date of 14 March 1962 and the application on the '579 patent had a continuation-in-part filing date of 1 August 1966.

bridges and OH groups react with polyisocyanates. One skilled in the art could look at MEGSON, MARTIN and the Rothrock patent, analyze their teachings in light of Shepard and the British Patent, and conclude that a polybenzylic ether resin could be plugged into Shepard to produce a phenolic urethane foundry binder.

The court found that Delta had sustained its burden of proving that one of ordinary skill in the art of phenolic chemistry would have found it obvious to use tertiary amines to promote the reaction between the Pep resin and polyisocyanates. J. SAUNDERS & K. ERISCH, POLYURETHANES: CHEMISTRY AND TECHNOLOGY (Interscience Pub. 1962, reprint 1978), teaches that at low temperatures "one normally uses a catalyst such as a tertiary amine or aluminum chloride to promote this reaction." Further, Shepard's '571 and '122 patents, and U.S. Patent Nos. 3,242,107, 3,282,896, and 3,043,794 disclose that tertiary amines in lieu of or in addition to heat promote the reaction between phenolic resins and polyisocyanates.

The court also found that Delta had sustained its burden of proof to show that the use of a curing agent with a pKb value of about 7 to about 11 to promote the reaction between the Pep resin and polyisocyanates would have been obvious to one of ordinary skill. The SAUNDERS reference disclosed work carried out in the 1940s involving catalysts with the pKb range as claimed in claim 17 of the '392 patent which showed that base strength is a controlling factor of a catalyst's effectiveness in urethane formation. Moreover, the Shepard patents and U.S. Patent Nos. 3,156,659 3,063,964, and 2,906,717 disclosed the use of various catalysts with a pKb value in the range of claim 17 to promote the reaction between phenolic resins and polyioscyanates.

d. Secondary Considerations:

The court, citing to *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied* 105 S.Ct. 172 (1984), and *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983), stated that it had considered relevant secondary considerations before reaching the conclusion that the Robins' patents would have been obvious. The court noted that there were no independent secondary considerations relevant to the '797 patent apart from its use in Isocure, the commercial foundry mix patented under the '579 patent, and Pep Set, the commercial foundry mix patented under the '392 patent.

The court found the commercial success of Isocure and Pep Set impressive, noting that Ashland had sold millions of pounds annually of these products, and that both products enjoyed an increasing market share. While noting that Ashland had granted licenses under these patent to Combustion Engineering Company and International Minerals and Chemical Company, the court further found that after Ashland lost the Milwaukee litigation Combustion Engineering sought a declaratory judgment that the patent claims here in suit were invalid, and subsequently settled for a renegotiated royalty rate decrease from 12.5% to 5%. International Minerals was found to have gone out of the business approximately one year after it was granted a license.

The court noted that Ashland had offered proof that Isocure and Pep Set had received recognition from the foundry industry in the form of awards and write-ups in trade publications. The court, however, found this recognition directed more towards the marketing of, rather than the invention of, these products. The court found it significant that Dr. Robins had not received any recognition from the industry and only $200 from Ashland for his role in developing Isocure and Pep Set.

The court stated that the law is well established that commercial success alone, or combined with other secondary evidence, is insufficient to establish patentability where primary indicia of patentability is lacking. After weighing Isocure and Pep Set's secondary considerations including commercial success against the primary indicia of obviousness — disclosures in the prior art — the court concluded that all the patent claims in suit were invalid for obviousness.

OPINION

A determination of whether the subject matter of claims in issue would have been obvious under 35 U.S.C. §103 involves factual findings with respect to: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) where relevant, objective evidence of nonobviousness, e.g., long-felt need, commercial success, failure of others, copying, unexpected results, i.e., the secondary considerations. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 674 (Fed. Cir. 1984); *Jones v. Hardy*, 727 F.2d 1524, 1527, 220 USPQ 1021, 1023 (Fed. Cir. 1984); *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 172 (1984). These factual findings serve as the foundation upon which the court bases its ultimate conclusion regarding the obviousness of the claimed subject matter as a whole. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 890, 221 USPQ 1025, 1033 (Fed. Cir. 1984). This court reviews the ultimate conclusion of obviousness as one of law on which it must exercise independent judgment. *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 1573, 220 USPQ 584, 589 (Fed. Cir. 1984).

A patent is presumed valid, and the burden of establishing invalidity as to any claim of a patent rests upon the party asserting such invalidity. 35 U.S.C. §282 (1982). The presumption of validity is a procedural device that mandates that the party asserting invalidity bears the initial burden of establishing a *prima facie* case of obviousness under 35 U.S.C. §103. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534, 218 USPQ 871, 875 (Fed. Cir. 1983). Once a *prima facie* case has been established, the burden shifts to the patentee to go forward with rebuttal evidence showing facts supporting nonobviousness. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 USPQ 177, 178, No. 84-1237, slip op. at 5, (Fed. Cir. September 5, 1985); *accord, In re Piaseki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). The party asserting invalidity, however, always retains the burden of persuasion of the issue of obviousness until a final judgment is rendered. *Hughes Aircraft Co. v. Untied States*, 717 F.2d 1351, 1359, 219 USPQ 473, 478 (Fed. Cir. 1983); *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875. Each fact forming the factual foundation upon which the court bases its ultimate conclusion regarding the obviousness of the claimed subject matter as a whole must be established by clear and convincing evidence. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984); *SSIH Equipment Co. S.A. v. United States International Trade Commission*, 718 F.2d 365, 375, 218 USPQ 678, 687 (Fed. Cir. 1983).

On appeal, however, the party subject to the adverse judgment on the issue of validity, in this case the patentee Ashland Oil, bears the burden of showing either that the district court committed reversible legal error in its ultimate conclusion as to obviousness, or that the district court's probative factual findings underlying its ultimate conclusion on obviousness were clearly erroneous.[13] *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 USPQ 26, 30 (Fed. Cir. 1985).

A. CLAIM 10 OF THE '797 PATENT — PEP RESIN

The district court found that the Pep resin of claim 10 contained some three ring and greater molecules, along with a substantial amount of one and two ring adducts, that the process taught by the Rothrock patent produces claim 10 material, although having a large portion of adducts and only a small amount of three ring or greater molecules, that MEGSON taught phenol-formaldehyde resins having an ortho-ortho orientation, connected by ether bridges and having an open para position, and that MARTIN taught a linear polymeric ether resin having up to thirty-five phenol rings linked by ether bridges, some of these ether linkages breaking down at higher temperatures to produce methylene linkages and formaldehyde. Based upon these findings, the court concluded that the Pep resin of claim 10 of the '797 patent would have been obvious to one of ordinary skill in the art inasmuch as the Rothrock patent, MEGSON, and Martin collectively suggested the critical elements of Pep resin here at issue.

Before reviewing the factual findings made by the district court with respect to the teachings of each of the individual references, and the propriety of combining the teachings of these references, we find it appropriate to address several statements made by the district court. *See Union Carbide Corp.*, 724 F.2d at 1574, 220 USPQ at 590 (while faulty reasoning may lead to a wrong result, appellant must show not only error in reasoning but error in result).

[13] A finding is clearly erroneous when the appellate court, after reviewing the entire record, is left with the definite and firm conviction that a mistake has been made, even though there is some evidence in the record to support such a finding. *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395, 76 USPQ 430, 444 (1948); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984).

Further guidance as to the role of appellate review under the clearly erroneous standard has been provided by the Supreme Court in *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504, 1511, 1512 (1985), wherein the Court stated that:

> This standard plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently.
>
> * * * * * *
>
> If the district court's account of the evidence is plausible in light of the record reviewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

A.1 Combining References

First, the court stated that Ashland had failed to establish that one of ordinary skill in the art would have been unable to read the prior art references and "discover" the Pep resin claimed by Robins. The law does not impose a burden on Ashland to establish that the *combined* teachings of the individual prior art references would not have led one skilled in the art to discover the Pep resin of claim 10. The ultimate burden of establishing invalidity rests upon the party espousing such. *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875. Where the party asserting invalidity must rely upon a combination of prior art references to establish invalidity, that party bears the burden of showing some teaching or suggestion in these references which supported their use in combination. *W.L. Gore*, 721 F.2d at 1552, 220 USPQ at 312. It is legal error to place this burden on the patentee.

A.2 35 U.S.C. §282

Further, if this statement is interpreted to place upon the patentee the burden of establishing the validity of his patents, it is at odds with established case law. Section 282 of Title 35 places the burden for the initial production of evidence, *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875, and the ultimate burden of persuasion on the issue of validity on the party asserting patent invalidity. *Hughes Aircraft*, 717 F.2d at 1359, 219 USPQ at 478; *Stratoflex*, 713 F.2d at 1534, 218 USPQ at 875. While the burden for the production of evidence shifts to the patentee once a *prima facie* case of invalidity is established, *Ralston Purina*, 227 USPQ at 178, slip op. at 5; *Piaseki*, 745 F.2d at 1472, 223 USPQ at 788, the ultimate burden remains with the party asserting invalidity, in this instance Delta, to establish that the claims of the patents here at issue are invalid. There is no burden on Ashland to establish that the claims of these patents are valid, and it is impermissible for a trial court to shift this burden to the patentee. *Jones*, 727 F.2d at 1528–29, 220 USPQ at 1025.

A.3 Evidence vis-a-vis Obviousness

The court also held that Ashland's evidence was insufficient to rebut Delta's clear and convincing evidence on the obviousness of claim 10 of the '797 patent. While on this record we cannot say that this holding by the district court was erroneous, it is open to an interpretation [14] at odds with the established case law, and for this reason we set forth a brief explication of the relevant legal principles. All facts relevant to the issue of obviousness, both the facts established by the party asserting invalidity *and* the facts established by the rebuttal evidence submitted by the patentee, must be fully considered by the court *prior* to reaching its conclusion on obviousness. *W.L. Gore*, 721 F.2d at 1555, 220 USPQ at 314; *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879. These facts must be established by clear and convincing evidence. *Lindemann Maschinenfabrik*, 730 F.2d at 1459, 221 USPQ at 486; *SSIH Equipment*, 718 F.2d at 375, 218 USPQ at 687.

A.4 The Pep Resin

The claims of a patent measure and define the invention. *Jones*, 727 F.2d at 1024, 220 USPQ at 1024. A §103 determination requires an evaluation of the prior art references with respect to the claimed invention. *Lear Siegler*, 733 F.2d at 890, 221 USPQ at 1033; *Union Carbide*, 724 F.2d at 1574–75, 220 USPQ at 590–91. The claims here in issue are to be read and construed [15] in light of the specification and prosecution history of the patent. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 932 (Fed. Cir. 1984). The district court found that the Pep resin of claim 10 contained some three ring and greater molecules, along with a substantial amount of one and two ring adducts. This finding is clearly erroneous, being based upon a misconstruction of the governing law and an interpretation of claim 10 which is erroneous as a matter of law. *Cf. Lemelson v. United States*, 752 F.2d 1538, 1552, 224 USPQ 526, 534 (Fed. Cir. 1985).

[14] One possible interpretation of the district court's holding is that the district court evaluated the facts established by Ashland's rebuttal evidence solely on the basis of its ability to overcome or knock-down the legal inference of obviousness, i.e., Delta's facts establishing a *prima facie* case for obviousness. This approach was rejected in *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976), wherein the court stated that facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion of obviousness, i.e., the *prima facie* case, was reached, not against the conclusion, itself. *See Ralston Purina Co. v. Far-Mar-Co, Inc.*, 227 USPQ 177–178, No. 84–1237, slip op. at 5 (Fed. Cir. September 5, 1985). The ultimate conclusion on obviousness must rest upon an evaluation of *all* facts that have been established by clear and convincing evidence.

[15] Claim interpretation is a legal matter subject to review free of the clearly erroneous standard applicable to fact findings. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), *cert. denied*, 105 S.Ct. 127 (1984).

The novel phenol-aldehyde resin *as claimed* in claim 10 is a linear phenolic resin wherein the sum of m and n must be at least two such that the phenolic resin as claimed comprises only molecules having three or more linked-phenol rings. Claim 10 does not claim one or two ring adducts, i.e., dimethylol phenols, benzylic ethers or methylene-bridged diphenols.[16] Relevant prior art for this §103 determination requires references which disclose phenolic polymers having three or more phenol rings, phenol rings linked by benzylic ether and methylene bridges, and phenol chains having at least one terminal methylol group.

A.5 Opinion Testimony

While objective factual evidence going towards a §103 determination is preferable to statements of opinion on the issue, the nature of the matter sought to be established, as well as the strength of the opposing evidence, must be taken into consideration in assessing the probative value of expert opinion. *In re Oelrich*, 579 F.2d 86, 91, 198 USPQ 210, 215 (CCPA 1978). Opinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight. *See* FED R. EVID, 701–704; *Orthopedic Equipment Co. v. United States*, 702 F.2d 1005, 1012, 217 USPQ 193, 199 (Fed. Cir. 1983). Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination. *Cf. In re Altenpohl*, 500 F.2d 1151, 1158, 183 USPQ 38, 44 (CCPA 1974). While the opinion testimony of a party having a direct interest in the pending litigation is less persuasive than opinion testimony by a disinterested party, it cannot be disregarded for that reason alone and may be relied upon when sufficiently convincing. *Cf. In re McKenna*, 203 F.2d 717, 720, 97 USPQ 348, 350–51 (CCPA 1953).

The district court found that the process disclosed in the Rothrock patent produced claim 10 material having a large portion of adducts, with only a small amount of three phenol ring or greater molecules. The bases for this finding were the objective teachings disclosed in the Rothrock patent, the opinion testimony given by Jordan Kopac, Delta's CEO, who although not qualified as an expert was within the category of one skilled in the art as found by the district court, *see supra* note 11, and the opinion testimony of Dr. Robert Conley, Ashland's expert witness. The court did not make any explicit credibility determinations with respect to the opinion testimony of Mr. Kopac and Dr. Conley, nor did the court give any indication as to the weight accorded this testimony.

A.6 The Rothrock Patent

The Rothrock patent disclosed a *process* for forming a heathardening unmodified phenol-formaldehyde resin.[17] There was no disclosure or teaching as to the chemical structure of this phenol-formaldehyde resin, i.e., what product was formed through the use of this process. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. The district court did not point to any supporting statements or teachings in the Rothrock patent as a basis for its finding that the process of Rothrock produced a claim 10 phenolic resin.

[16] The specification of the '797 patent teaches the formation of novel phenolic compositions characterized as a phenol-formaldehyde adduct or modified resole resin, which comprises one-ring dimethylol phenols and two-ring benzylic ethers and methylene-bridged phenols. The specification, however, also discloses that the novel phenolic resin of claim 10 is a higher molecular weight product formed by the condensation of the phenol-formaldehyde adduct. Further, the specification teaches that the "formulation of the [phenol-formaldeyde] Adduct ... is a precursor to the novel phenolic resins [as claimed in claim 10]."

While the specification is silent as to the actual chemical composition of phenol aldehyde reaction products produced by practicing the process disclosed in the '797 patent, Dr. Robins, the inventor, testified that the phenol aldehyde reaction product resulting from this process would comprise approximately 5–10% phenol formaldehyde resin as claimed in claim 10, with the remainder being monomers such as dimethylol phenols, benzylic ethers and methylene-bridged phenols.

The actual chemical composition of the reaction products produced by the '797 process, however, is irrelevant to a §103 determination with respect to the *product* claimed in claim 10. The metes and bounds of claim 10 define the relevant product for the §103 determination. *Lear Siegler*, 733 F.2d at 890, 221 USPQ at 1033.

[17] The Rothrock patent taught only that the phenolformaldehyde resin produced by the process disclosed therein was cured or heat-hardened by the addition of thermal energy to the resin. There was no disclosure that the resin was curable at room temperatures by the addition of an acid catalyst. The specification of the '797 patent, in contrast, teaches that the Pep resin is curable at room temperatures by the addition of an acid catalyst, or may be cured by the addition of thermal energy to the resin. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311 (a reference must have been considered in its entirety, for disclosures which taught way from the invention as well as disclosures which directed one skilled in the art towards the claimed subject matter).

Each element of a claim is material. *Lemelson*, 752 F.2d at 1551, 224 USPQ at 533. The process for producing the phenolic resin as claimed in claim 10 of the '797 patent requires the removal of water above 100 °C during the process.[18] This removal of water occurs during the condensation stage of the '797 process wherein the previously formed phenol-formaldehyde adduct is condensed to form the claim 10 product. The specification of the '797 patent teaches the importance of removing water during the condensation step.[19] There was no teaching in the Rothrock patent that water was to be removed *during* the disclosed process.[20]

There is no presumptive correlation that two similar processes form substantially the same product where the processes differ by a materially limiting step. *Cf. In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968) (if the prior art of record failed to disclose a method for making a claimed compound, at the time the invention was made, it cannot be legally concluded that the compound itself was in the possession of the public).

There was no objective evidence to be gleaned from the Rothrock patent which would have supported a factual finding that the Rothrock patent produced claim 10 material. Concomitantly, there was no factual support for Mr. Kopac's opinion testimony with respect to the Rothrock patent, and consequently, Mr. Kopac's opinion testimony is of little probative value in a validity determination. *Altenpohl*, 500 F.2d at 1158, 183 USPQ at 44. Accordingly, the district court committed clear error when it found that the Rothrock process produced claim 10 material.[21]

A.7 The MARTIN Reference

MARTIN, the court found, disclosed a linear polymeric ether resin containing up to thirty-five phenol rings linked in an ortho, ortho orientation by other bridges. A reference, however, must have been considered for all it taught, disclosures that diverged and taught away from the invention at hand as well as disclosures that pointed towards and taught the invention at hand. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. While MARTIN taught a polymer having the phenol rings linked together by benzylic ether bridges, as well as at least one terminal methylol group, MARTIN also taught that this polymer had an "R" substituent at the para position. MARTIN taught that this R group was a substituent other than hydrogen. The polymeric resin of claim 10, in contrast, has an open or unsubstituted para position. Not only was the para position of the MARTIN compound blocked, there was no recognition that it would have been advantageous to replace the R substituent with a hydrogen, i.e., unsubstituted para position, to increase the polymer's reactivity.

A.8 The MEGSON Reference

The court found that the MEGSON reference illustrated a polybenzylic ether within the scope of claim 10, the drawing showing a phenol-formaldehyde resin molecule having ether bridge linkages at the ortho-ortho position and an open para position. The court found this molecule satisfied the m, n limitations of claim 10 by having at least two benzylic ether linking bridges, i.e., m equal to or greater than two while n equals zero.[22] But,

[18] *See supra* note 16 and accompanying text.

[19] The presence of water results in reaction products which cannot be cured to mechanically strong resins by the use of acidic reagents at room temperature. The presence of water affects not only the activity of the catalyst, but also the structure of the product formed, for example, permitting substitution at the para position.

[20] This statement will be more fully addressed in Section "B. THE PROCESS CLAIMS OF THE '797 PATENT", *infra*.

[21] The district court's factual finding that the process of the Rothrock patent produced claim 10 material is not plausible in light of the entire record. *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504, 1512 (1985). There is no objective evidence disclosed in the Rothrock patent as to the nature of the product formed by the process disclosed therein. Delta did not proffer any objective evidence as to the type of phenolic resin produced by the Rothrock process. Mr. Kopac's opinion testimony as to what the Rothrock produced is not substantiated by any objective evidence, and therefore can have probative value only as conjecture of one skilled in the art. *See* FED. R. EVID. 701. The evidence of record does not support the view of that the Rothrock process produced claim 10 material. *Id.*

[22] While we have reservations about this interpretation of claim 10, we will not, on the record before us, say it is erroneous as a matter of law. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 932. Under the court's interpretation when n is equal to zero, i.e., no methylene bridges, the ratio of m to n is undefined. But, whenever methylene bridges are present, i.e., n is a real number unequal to zero, the ratio of m to n is a finite real number. It is questionable whether the ratio of m to n would be a finite real number in all circumstances except one, where it is undefined.

The specification of the '797 patent indicates that the majority of linkages between the phenol rings will be benzylic ether such that the remainder of the linkages will be methylene. The specification also teaches that, at the temperatures at which condensation occurs to form the claim 10 material, some methylene linkages are formed.

Dr. Robins, however, gave testimony that n could equal zero, but this testimony was elicited in connection with a discussion as to whether the dimethylol phenols, benzylic ethers and methylene-bridged phenols are within the scope of claim 10. Dr. Robins also testified that the scope of claim 10 did not encompass the one or two phenol-ring adducts, but only polymers having three or more phenol rings. Dr. Conley, Ashland's expert, also testified that n could be equal to zero. *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504, 1512 (1985) (where there are two permissible views of the evidence, the fact finder's choice between them cannot be clearly erroneous). The court's interpretation of this claim appears to have been predicated on the factual testimony proffered by Ashland's witnesses.

the MEGSON reference should also have been considered for disclosures that taught away from the invention here at issue. *Id.*, 220 USPQ at 311. The specific disclosure relied upon by the district court depicted two polymers cross-linked by a methylene derivative. Since this particular cross-linking mechanism was postulated to involve a reaction with nuclear hydrogen, the phenols of the polymers were shown as para unsubstituted, i.e., having hydrogen at the para position. The other cross-linking mechanisms, as well as a disclosure of a benzylic ether linked polymer product, depicted polymers having an "R" group at the para position. This R could have stood for hydrogen, or it could have stood for an organic radical.[23] There was no teaching in the explication of the cross-linking mechanism as to what the terminal end groups of these cross-linking structures were, i.e., there was no teaching that these cross-linking structures had a methylol terminal end group. Finally, there was uncontroverted testimony by Ashland's expert, *see supra* note 23, that the disclosure in the MEGSON reference relied upon by the district court was a hypothetical structure.

The test of whether a particular compound described in the prior art may have been relied upon to show that the claimed subject matter at issue would have been obvious is whether the prior art provided an enabling disclosure with respect to the disclosed prior art compound. *Cf. In re Donohue*, 766 F.2d 531, 533, 226 USPQ 615, 621 (Fed. Cir. 1985); *Hoeksema*, 359 F.2d at 273-74, 158 USPQ at 598-99. Delta did not offer evidence that showed an enabling disclosure for the disclosed structure of MEGSON, while uncontroverted testimony showed the MEGSON structure to be a hypothetical structure.

[23] Dr. Conley testified that Megson's original work on this subject taught that the R group was an alkyl or aryl constituent. He also testified that the drawing cited by the district court, as well as the other two drawings relating to the cross-linking mechanism, were postulated or hypothetical structures to explain the cross-linking mechanism.

A.9 Conclusion

The district court concluded, in light of the Rothrock patent, MEGSON, and MARTIN, that the Pep resin as claimed in claim 10 of the '797 patent would have been obvious. Obviousness, however, cannot be established by combining the teachings of the prior art to produce the claimed invention, unless there was some teaching, suggestion or incentive in this prior art which would have made such a combination appropriate. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933; *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311. The district court did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination, nor in fact did the district court even point out what teachings from each of the references, when considered in combination, were relied upon in concluding that the invention of claim 10 would have been obvious. Nor apparently did the district court give any consideration to teachings in these references which would have led one skilled in the art away from the invention of claim 10. We would have to say that the district court used claim 10 of the '797 patent as a blueprint, and abstracted individual teachings from the Rothrock patent, MEGSON, and MAKTIN to create the Pep resin of claim 10. *W.L. Gore*, 721 F.2d at 1552, 220 USPQ at 312. This was error as a matter of law.[24]

We are not persuaded, based upon the foregoing, that the facts upon which the district court based its legal conclusion that the subject

[24] To properly combine references A and B to reach the conclusion that the subject matter of a patent would have been obvious, case law requires that there must have been some teaching, suggestion, or inference in either reference A or B, or both, or knowledge generally available to one of ordinary skill in the relevant art, which would have led one skilled in the art to combine the relevant teachings of references A and B. *See, e.g., ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 993; *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311; *In re Sernaker*, 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed. Cir. 1983). The decision maker's determination as to what objective evidence in reference A or B, or both, or generally available to one of ordinary skill in the relevant art, is of the nature of a factual finding.

The decision maker, however, after making findings as to the objective evidence, must subjectively analyze these factual findings to determine whether the teachings of references A and B could have been combined. Thus, the ultimate determination as to whether references could have been combined is a legal conclusion.

Where the district court fails to set forth the objective bases for its conclusion that references could have been combined, this court will review the determination as a matter of law.

matter of claim 10 of the '797 patent would have been obvious were proven by clear and convincing evidence, *Lindemann Maschinenfabrik*, 730 F.2d at 1459, 221 USPQ at 486; *SSIH Equipment*, 718 F.2d at 375, 218 USPQ at 687, such that it cannot be said that Delta had satisfied its burden of proof. Nor was there a sufficient basis for the district court to combine the teachings of the Rothrock patent, MEGSON, and MARTIN. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933. The district court erred as a matter of law in concluding that the invention of claim 10 would have been obvious.

B. THE PROCESS CLAIMS OF THE '797 PATENT

The district court found that the Rothrock patent described a process for manufacturing phenol-formaldehyde resins wherein: (1) a formaldehyde/phenol ratio greater than 1 was taught; (2) the use of paraformaldehyde, the anhydrous form of formaldehyde, was disclosed; (3) a temperature range of 100-120°C was taught; (4) the removal of water was taught in certain examples; and (5) the use of soluble metal salt catalysts including zinc acetate was disclosed. One point of contention [25] as to what the Rothrock patent disclosed was whether Rothrock taught one skilled in the art the removal of water during the process which was consonant in scope to the water-removal limitation of the '797 process claims.

B.1 Robins' '797 Process

Process claim 1 of the '797 patent, an independent claim, describes a material claim limitation which requires the phenolic-resin producing reaction to be conducted "under substantially anhydrous conditions with the removal of water above 100°C." The materiality of this limitation is disclosed in the '797 specification wherein it is stated that the "failure to *continuously* remove water not only affects the activity of the catalysts, but also the structure of the product formed, in permitting, for example, para-substitution," and that "the presence of water results in reaction products which cannot be cured to mechanically strong resins by the use of acidic agents at room temperature." (Our emphasis). The specification further discloses that the "process of the present invention is carried out in equipment which will provide for the *continuous* removal of water from the reaction mixture." (Our emphasis). The water-removal limitation of the process claims of the '797 patent, therefore, requires that water be continuously removed during the polymer formation stage of the reaction, *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 932 (the claim here in issue is read and construed in light of the specification), i.e., at temperatures above 100°C where the phenol-formaldehyde adduct—a mixture of dimethylol phenols, benzylic ethers and methylene-bridged phenols—is condensed to form the three-ring or greater phenolic resin.

B.2 The Rothrock Process

In contrast, the Rothrock patent in general did not teach or suggest the removal of water during the process described therein, nor was there any teaching or suggestion that the removal of water during the process was a critical limitation. More particularly, there was no teaching or suggestion that water was to be removed during the phenolic resin formation stage of the reaction, i.e., at temperatures above 100 °C. Only Example I of Rothrock disclosed a removal of water, teaching that a small amount of water which had formed on the sides of the reaction flask was removed from the resulting clear liquid formed by the process.[26] This water was removed, however, after the resin of the process had been formed, i.e., at temperatures well below 100 °C. The equipment for the process of Rothrock as disclosed in the examples did include an air condensor.[27] Mr. Kopac testified that there was no disclosure or teaching in the Rothrock patent of the function being performed by the air condensor, and that it could not be said with any certainty that the air condensor functioned to remove or retain water in the reaction zone during the Rothrock process. Examples II, III, IV and VII of the Rothrock patent disclosed that the reaction mixture was heated at reflux.[28]

This disclosure would have suggested to one skilled in the art that water was not removed, nor was there any necessity for doing so, during the reaction process of Rothrock. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311 (a reference must have been considered in its entirety, for disclosures which taught away from an invention as well as disclosures which directed one to the invention). There was no clear teaching or suggestion in Rothrock that water was to be removed at any step during the condensation process disclosed therein, but rather only after the phenolic condensation was completed. Moreover, the Rothrock reference as a whole suggested that water was retained during the reaction process. *See supra* note 27 and text following, and note 28.

The district court found that the Rothrock patent had not taught the removal of water above 100° C. Yet, the district court subsequently found that one of ordinary skill could have read Rothrock and recognized that varying the solvent in Example V and removing water—as Rothrock had done in Examples I and VII [29] —yielded a process which could have been substantially similar to the '797 process. These findings by the court are in direct conflict. Since the '797 process claims contain a material limitation directed to "the removal of water above 100° C", *Lemelson*, 752 F.2d at 1551, 224 USPQ at 533, and since the district court found that Rothrock did not teach removal of water above 100° C, there was no basis for the court's finding that the Kothrock process was substantially similar to the '797 process since the Rothrock process lacked this material limitation. *See supra* note 21. Accordingly, we hold that this finding of the district court is clearly erroneous.

B.3 The Japanese Patent

The Japanese Patent, the court found, described a process for producing phenol-formaldehyde initial condensates, by reacting phenol and formaldehyde: (1) under anhydrous polymerization conditions, i.e., starting with paraformaldehyde and removing water; (2) at temperatures above 100 °C and as high as 120 °C; and (3) using soluble metal salts as catalysts. Further, the district court found that although the examples in the Japanese Patent taught a formaldehyde/phenol ratio less than 1, the specification taught that this ratio could be greater than 1.

While the process disclosed in the Japanese Patent did teach the use of paraformaldehyde, or another substance having the same effectiveness, and the continuous removal of water, the Japanese Patent should have been considered in its entirety, with due consideration given to disclosures that diverged or taught away from the invention here at issue, as well as disclosures which directed one skilled in the art to the invention. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311.

The Japanese Patent disclosed a process for producing a phenol-formaldehyde initial condense in which phenol was added to a polar solvent such as ordinary alcohol, paraformaldehyde or a substance having similar effectiveness was dissolved into the phenol directly in a molar ratio range of 0.5 - 1.5 of formaldehyde/phenol, and this mixture was reacted in the presence of a weak alkaline catalyst[30] with the continuous elimination of water to produce a liquid mixture of 2-methylolphenol or 2-methylolphenol and 2, 6-dimethylolphenol. This resulting liquid mixture was then acidified to induce a condensation reaction to form 2, 2'-dihydroxydiphenyl methane and/or other methylolation products. The specification further taught that the hydroxide induced the ortho orientation of formaldehyde in a non-water system and that alkoxyphenoxymethane accelerated the ortho

[25] The Rothrock patent taught that formaldehyde and phenol were condensed in the presence of a mild acid catalyst *and* a completely volatile, non-gum-forming solvent selected from the class of monohydric aliphatic alcohols and mononuclear aromatic hydrocarbons. Presented testimony, and argued before the district court and this court, that the use of butyl alcohol as the rothrock solvent produced a butyl alcohol modified resin which was not a phenolic resin. The district court made a finding of fact to this effect. Ashland, however, has ignored the teaching of Rothrock that mononuclear aromatic hydrocarbons could have been used as the solvent, and that Example V taught the use of toluene, an aromatic hydrocarbon.

Although the process claims of the '797 patent do not have a specific limitation directed to a solvent, the process claims do require that the phenol and aldehyde be "in the liquid phase." The '797 specification teaches that "[a]lthough it is not necessary to have an inert diluent present, it is generally preferred to conduct the reaction in the presence of one." The '797 specification further teaches that these solvents, when used, are non-polar organic solvents such as aliphatic, cycloaliphatic, aromatic and halogenated hydrocarbons. Toluene is set forth as a specific example of such a solvent.

[26] Contrary to the district court's statement, Example VII of the Rothrock patent did not teach the removal of water. The only statement in Example VII with respect to water was that after the completion of the process, a clear solution was obtained "with traces of water on the sides of the flask."

[27] Mr. Kopac testified that an air condensor may be used, and depending upon its length, will condense certain vapors formed during the reaction in a manner so as to reintroduce these condensed vapors back into the reaction zone while unwanted vapors are transported outside of the reaction zone.

[28] Dr. Robins' uncontroverted testimony was that reflux meant that water was being distilled from the reaction mixture, condensed, and returned to the reaction mixture.

[29] *But see supra* note 26.

[30] At one point in the specification the Japanese Patent taught that the alkaline catalyst could be selected from a group consisting of alkaline earth metal hydroxides, magnesium hydroxide, and alkoxyphenoxymethanes — the process disclosed therein was claimed in this manner — while at another point in the specification it was taught that both an alkaline catalyst and the alkoxyphenoxymethanes were used to produce the initial methylolphenol products.

linkage during condensation.[31] The specification further taught that the process reaction could have been effected without dissolving the phenol in a polar solvent, i.e., a solvent need not be used.

In contrast, the '797 specification teaches that the soluble, metal salt catalyst is a metal-ionically bonded to a salt radical, and that this salt radical should be that of a stronger acid, one having a dissociation constant greater than 10^{-8}, to prevent cross-linking during the formation of the reaction product. Further, while the process claims of the '797 patent do not incorporate a specific limitation calling for the use of a solvent, the specification discloses that in the preferred embodiment of the process a non-polar organic solvent is utilized. While the Japanese Patent taught that the use of a solvent was optional, it also taught that when a solvent was used, it must have been a polar solvent. *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311.

To the extent that the district court concluded that the Japanese Patent by itself would have rendered the subject matter of the process claims of the '797 patent obvious, this conclusion is erroneous as a matter of law. The Japanese Patent clearly taught, at a minimum,[32] that an alkaline catalyst, to induce the ortho orientation of the formaldehyde, was a material element of the process. *See supra* note 31. Moreover, the reaction of this process was a two stage reaction wherein the reactants were first exposed to an alkaline catalyst, and the resulting liquid mixture was then acidified to produce the final reaction product. The process claims of the '797 patent, in contrast, do not use an alkaline catalyst, nor is the '797 process a two stage reaction for the formation of a phenolic resin which requires initial reaction of the phenol and formaldehyde with an alkaline catalyst, and then the acidification of the resulting liquid mixture.

To the extent that the district court concluded that the teachings of the Japanese Patent could have been combined with the teachings of the Kothrock Patent to reach the conclusion that the subject matter of the '797 process claims would have been obvious, this conclusion is erroneous as a matter of law. *See supra* note 24. The district court did not point to any teachings or suggestions in either reference which would have led one skilled in the art to perceive an advantage to be derived from their combination. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933; *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311. In point of fact, the teachings of the two references would have led one skilled in the art away from their combination. Rothrock taught that his process could not be practiced using an alkali earth metallic hydroxide catalyst. In contrast, the Japanese Patent required such a catalyst. Rothrock required the use of a solvent, which could have been either polar or non-polar while the Japanese Patent taught that the use of a solvent was optional. Further, the Japanese Patent taught that when a solvent was used, it must be polar. The Japanese Patent also taught that the formaldehyde/phenol ratio could have a range of 0.5–1.5 while Rothrock required that the ratio must be greater than 1.

B.4 The Fraser Reference

The district court found that the Fraser reference taught the effectiveness of zinc and lead as catalysts to form ortho-ortho linked phenol-formaldehyde chains and that ether bridges were formed at reaction temperatures below 140° C. The court also found, however, that the Fraser reference did not teach the removal of water above 100° C and that the method of Fraser did not produce compounds having more than two phenol rings.

A reference, however, should also have been considered for its antithetical teachings. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. One of the critical teachings of Fraser was that the formaldehyde/phenol ratio must be less than 1, i.e., a molar excess of phenol was required for the method. It would be error as a matter of law if the district court concluded that the subject matter of the process claims of the '797 patent would have been obvious in view of the Fraser reference alone. Nor was there any teaching or suggestion that would have led one skilled in the art to combine the teachings of the Fraser reference with either

[31] Delta argued that the Japanese Patent emphasized the importance of removing water in the process to produce the ortho-ortho orientation of the resultant phenolic resin. The Japanese Patent, however, taught that "in order to provide the ortho orientation to the resin, it is, of course necessary to select the catalyst having the ortho orientation effect. . . ." Although it was taught that both the pH and water content of the reaction system affected the final product, the Japanese Patent clearly indicated that the alkaline catalyst was the dominant factor in producing the ortho-ortho orientation. Since the Japanese Patent disclosed that it was the anhydrous conditions and the alkaline catalyst in combination which produced the ortho-ortho orientation in the resultant product, there was no suggestion or inference therein to one skilled in the art that the removal of water in the Rothrock process, which cannot utilize an alkaline catalyst, would have been advantageous in effecting an ortho-ortho orientation in the resulting resin. *W.L. Gore*, 721 F.2d at 1551, 220 USPQ at 311.

[32] *See supra note 30.*

the teachings of the Rothrock patent or the teachings of the Japanese Patent, or both. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933.

B.5 Conclusion

We held *supra* that the district court's finding that the Rothrock process was substantially similar to the process of the '797 patent was clearly erroneous. Further, we are not persuaded that the other facts, discussed *supra*, which the district court relied upon in reaching its legal conclusion that the subject matter of claims 1, 2, and 7 of the '797 patent would have been obvious, were proven by clear and convincing evidence, *Lindemann Maschinenfabrik*, 730 F.2d at 1459, 221 USPQ at 486; *SSIH Equipment*, 718 F.2d at 375, 218 USPQ at 687, such that it cannot be said that Delta had sustained its burden of proof before the district court. It was error as a matter of law for the district court to conclude that processes of claims 1, 2 and 7 of the '797 patent would have been obvious.[33]

C. THE CLAIMS OF THE '392 AND '579 PATENTS

Claim 17 of the '392 patent is directed to a foundry mix having sand as the major constituent and up to 10 percent by weight of sand of a resin composition. The resin composition comprises in admixture a benzylic ether resin substantially similar to the phenolic resin claimed in claim 10 of the '797 patent,[34] a hardener component defined as a liquid polyisocyanate, and a curing catalyst defined as a base having a pKb value in the range of about 7 to about 11. Claim 14 of the '579 patent is directed to a foundry mix similar to that of claim 17, except that the phenolic resin of the binder composition is the resin as claimed in claim 10 of the '797 patent, and the curing agent is defined as a tertiary amine. Claim 19 of the '579 patent is directed to a process for preparing foundry shapes using the foundry mix of claim 14.

[33] It appears that the district court used process claim 1 of the '797 patent as a blueprint, and abstracted individual teachings reference to create and process of claim 1, without due consideration for teachings in these references that would have led one skilled in the art to find it improper to combine these references. *W. L. Gore*, 721 F.2d at 1552, 220 USPQ at 312.

[34] The phenolic resin of claim 10 of the '797 patent is defined such that m and n are numbers the sum of which is at least 2 and the ratio of m to n is greater than 1. In contrast, the benzylic ether resin as claimed in the foundry mix of claim 17 of the '392 patent is defined such that m and n are numbers the sum of which is at least 2, and wherein m is at least 1.

C.1 General Level of Skill in the Art

The district court found that British Patent No. 1,031,909, although technically not prior art, was indicative of what was generally known during the relevant time frame to persons of ordinary skill in the foundry art. Finding that the British Patent described reacting novolac resins with highly reactive divalent materials[35] to produce soluble, fusible polymers which may be employed "as binders for sand (foundry resins)", the court concluded that the British Patent disclosed the use of phenolic urethanes as foundry binders.[36] The court also found that U.S. Patent Nos. 3,398,122 and 3,409,571 (the '122 and '571 patents, respectively), issued to Shepard, were significant for a teaching that phenolic urethanes were useful as constituents of foundry binders. Shepard, the court found, described a soluble thermoplastic, i.e, a novolac phenolic resin modified with a phosphorous compound, which could be mixed with polyisocyanates to form thermosetting products useful in foundy sand binders. Based upon the district court's findings with respect to the Shepard references, we cannot say that the district court erred in concluding that phenolic urethanes were taught as having utility in foundry binders.

C.2 The Shepard Patents

The district court found that one skilled in the art "could also readily sense that the 'Pep'

[35] The specification described these highly reactive divalent materials as "[a]ny diisocyanate in which the isocyanate groups are the sole reactive groups. . . ."

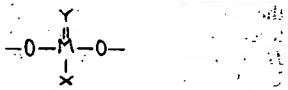
[36] Keeping in mind the admonishment that a disclosure should have been read in its entirety for all it divulged, *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311, we have reservations about this finding of the district court. The specification of the British Patent stated that "[a]s far as [the inventors] are aware, soluble, fusible polymers which are the products of the reaction of a novolac resin and a highly reactive divalent material capable of condensing with phenolic hydroxyl groups have not heretofore been performed." The specification further stated that "the reaction of a conventional novolac polymer with such divalent reactants results in the production of the expected insoluble, infusible thermoset materials." From these disclosures in the British patent we would not say it was a foregone determination that the use of phenolic urethanes, prepared by the reaction of a resin with an isocyanate, in foundry mixes was known to those of oridinary skill in the foundry art as of the critical date.

resin might be substituted into the Shepard patent." Since it was known in the prior art how ether bridges and hydroxyl groups reacted with polyisocyanates,[37] one of ordinary skill in the art could have looked at the Rothrock patent, MEGSON and MARTIN, analyzed their teachings in light of the Shepard patents and the British Patent,[38] and concluded that a polybenzylic ether resin could have been plugged into Shepard to produce a phenolic urethane foundry binder.

The district court's conclusion that the Pep resin might have been substituted for the phenolic condensate used in the Shepard patent is erroneous as a matter of law, for several alternative reasons.[39] First, the district court failed to consider the '571 patent in its entirety in particular for these teachings therein that would have led one skilled in the art away from the subject matter of the '392 and '579 patents. *W.L. Gore*, 721 F.2d at 1550, 220 USPQ at 311. The specification of the '571 patent taught that the thermoplastic products of the invention could be used to produce thermosetting products by curing the thermoplastic products with agents such as, *inter alia*, polyisocyanates. The specification disclosed further that these thermoplastic products and/or thermosetting products were useful as foundry sand binders.

But, the district court failed to consider what these thermoplastic products were disclosed to comprise. The '571 specification disclosed that these thermoplastic products were polymeric esters characterized in that:

(1) a major portion of the moiety of the member of the phosphorus family has the formula:



in which the unsatisfied bonds are attached to aryl nuclei of the same phenolic condensate, and in which M is an atom of the phosphorus family, Y is oxygen or sulfur, and X is halogen, hydroxyl, mercapto, hydrocarbyl, hydrocarbyloxy, halogen-substituted hydrocarbyl, halogen-substituted hydrocarbyloxy, or an aryloxy radical of the same phenolic condensate to which M is attached;

(2) at least 60 percent of the phenol-aldehyde or phenol-ketone condensate had o,o'-alkylidene linkages, and;

(3) the phenolic condensate has an average number of aryl nuclei per molecule in the range of 2.2 to 8.

Thus, the '571 specification taught that the thermoplastic product was more than a phenolic condensate. It was a phenolic condensate wherein a phosphorus-containing moiety had its unsatisfied bonds attached to the aryl nuclei of the same phenolic condensate. Even assuming arguendo that one skilled in the art might readily have sensed that the Pep resin of the '797 patent might have been used as the phenolic condensate called for by the Shepard patent, Shepard taught only that it was the polymeric ester or thermoplastic product, i.e., the phenolic condensate in combination with the bonded phosphorus-containing moiety, that could be reacted with polyisocyanates or tertiary amines to produce thermosetting products having utility in foundry sand binders. But, the teachings of Shepard did not disclose to one skilled in the art whether the phenolic condensate, by itself, would have had utility as a thermosetting product.

The district court found that one of ordinary skill in the art would have looked at the Rothrock patent, MEGSON, and MARTIN, analyzed their teachings in light of the Shepard and British patents,[40] and concluded that a polybenzylic ether resin could have been plugged into Shepard to produce a phenolic urethane binder. Based upon our holdings in Section "A. CLAIM 10 OF THE '797 PATENT — PEP RESIN," *supra*, this conclusion is erroneous as a matter of law. In Section A we held that the Rothrock patent, MEGSON, and MARTIN, considered singly would not have led to the conclusion that the Pep resin as claimed in claim 10 of the '797 patent would have been obvious, and that there was no basis for combining the teachings of these references, such that one skilled in the art would not have had knowledge of the Pep resin as of the critical period. Therefore, there was no proper basis for the district court to conclude that one skilled in the art, even with knowledge of the teaching of the Shepard patent with respect to the utility of phenolic urethanes as foundry binders, would have had knowledge of a phenolic resin substantially similar to the phenolic resin as claimed in claim 10 of the '797 patent. Therefore, it was erroneous to conclude that the Pep resin of the '797 patent could have been substituted into the Shepard patent for use in producing a phenolic urethane foundry binder as taught in the Shepard patent.

C.3 Combining Prior Art with the Shepard Patents

Moreover, assuming for the sake of argument that the Rothrock patent, MEGSON, and MARTIN would have led one skilled in the art to a phenolic resin substantially similar to the phenolic resin as claimed in claim 10 of the '797 patent, the '571 patent contained relatively little in the way of positive suggestion or inference which would have led one skilled in the art to combine the teachings of these references with the Shepard patent. *ACS Hospital Systems*, 732 F.2d at 1577, 221 USPQ at 933. The '571 patent taught two methods for the preparation of phenolic condensates having a high percentage of ortho-ortho alkylidene linkages.

The preferred phenolic condensate was prepared by reacting an excess of phenol with formaldehyde, i.e., a phenol/formaldehyde ratio greater than 1, in the presence of an inorganic alkali catalyst. In contrast, the Rothrock patent taught a formaldehyde/phenol ratio of 1:1, or a range of 1:63 to 1:1. Further, the Rothrock patent taught that the resins thereof could not be produced in the presence of alkali catalysts.

The alternative process for producing the phenolic condensates described in the '571 patent involved reacting an aldehyde with a phenol in the presence of an acid catalyst. The ratio of formaldehyde/phenol was described as being in the range of 0.5 to 1.0, with the preferred range being 0.7 to 0.9. Thus, while the '571 patent taught a formaldehyde/phenol ratio range wherein the upper bound minimally overlapped the lower bound of the Rothrock patent formaldehyde/phenol ratio, the preferred range taught in the '571 patent diverged away from the ratio as taught in Rothrock. The '571 patent also taught that the acid catalyst could be hydrochloric, sulfuric or oxalic acids, and was silent as to the need for a solvent to effect condensation. The Rothrock patent, in contrast, taught that condensation occurred in the presence of both a mild acid catalyst, such as zinc acetate, boric acid, or copper acetate, and a completely volatile, non-gum-forming solvent, and further that resins could not be produced in the presence of strongly acidic catalysts, such as hydrochloric acid. Since the '571 patent appeared to have suggested stronger acid catalysts than those usable in the Rothrock patent, and was silent as to the use of a solvent, an uncertainty would have arisen as to whether the teachings of the Rothrock patent could have properly been combined with the teachings of the Shepard patent.

A further point is that the '571 patent taught that the phenolic condensate of the novel ester was one having at least 60 percent ortho-ortho alkylidene linkages. The specification disclosed that the term alkylidene expressed the structural relationship of the substituted methylene residues of the aldehyde to the phenolic nuclei of the phenolic condensates and that the term was intended to be generic to all such substituted methylene groups defined within the scope of the invention, and further taught that the phenolic condensates most useful in the invention were characterized by R_1-C-R_2 linkages, wherein R_2 could be independently selected from the group consisting of hydrogen, a hydrocarbon radical, and a halogen-substituted hydrocarbon radical. This teaching would have seemed to preclude the teachings of the Rothrock patent being combined with the teachings of the '571 patent inasmuch as the phenolic resin of the Rothrock patent which would have been substantially similar to the resin as claimed to claim 10 of the '797 patent would have had a majority of ether linkages,[41] not alkylidene linkages.

D. SECONDARY CONSIDERATIONS

The district court stated that it had considered relevant [42] secondary considerations prior

[37] On appeal, both Ashland and Delta have pointed out that this statement by the district court is technically incorrect in part. While polyisocyanates do react with hydroxyl groups, they do not react with benzylic ether bridges.

[38] The district court made a finding that the British Patent was not prior art. Therefore, the district court could only have utilized the British Patent in the "analysis" to the extent that the British Patent showed the general level of skill in the art as of the critical date. *Cf. In re Farrenkopff*, 713 F.2d 714, 219 USPQ 1 (Fed. Cir. 1983). *But see supra* note 36.

[39] Based upon the discussion *infra*, it is not necessary to review the factual findings made by the district court with respect to tertiary amines and curing catalysts having a pkb value in the range of about 7 to about 11.

[40] *See supra* note 38.

[41] Claim 10 of the '797 patent requires that the phenolic resin claimed therein must have a ratio of m to n of greater than 1. To satisfy this constraint, m must be greater than n such that the number of benzylic ether bridges is always greater than 50 percent. The benzylic ether bridges are defined by the chemical formula CH_2-O-CH_2, and as such contain oxygen. In contrast, the specification of the '571 patent teaches that the preferred phenolic condensate must have at least 60 percent ortho-ortho alkylidene bridges, and that these bridges do not contain oxygen.

[42] Case law requires that a nexus be established between the merits of the claimed invention and the evidence proferred on secondary considerations, if the evidence on secondary considerations is to be given substantial weight in the calculus of obviousness/nonobviousness. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575, 222 USPQ 744, 746 (Fed. Cir. 1984), *cert. denied*, 105

to reaching conclusion that the subject matter of the claims in issue of the '392 and '579 patents would have been obvious. Thus, the district court seemingly recognized the holdings of this court vis-a-vis secondary considerations, to wit, that all relevant evidence going to the issue of obviousness/nonobviousness, which includes properly presented evidence on secondary considerations, must have been considered prior to reaching a conclusion on obviousness/nonobviousness. *Fromson*, 755 F.2d at 1556–57, 225 USPQ at 32; *W.L. Gore*, 721 F.2d at 1555, 220 USPQ at 314.

The district court, however, also averred that the law was well established that commercial success alone, or considered in combination with other secondary considerations, is insufficient to establish patentability where primary indicia of patentability was lacking.[43] Just as it is legal error for a district court to fail to consider relevant evidence going to secondary considerations, *Lindemann Maschinenfabrik*, 730 F.2d at 1461, 221 USPQ at 488, it may be legal error for a district court to presuppose that all evidence relating to secondary considerations, when considered with the other *Graham*[44] indicia relating to the obviousness/nonobviousness issue, cannot be of sufficient probative value to elevate the subject matter of the claimed invention to the level of patentable invention. *Fromson*, 755 F.2d at 1556–57, 225 USPQ at 32; *Union Carbide*, 724 F.2d at 1573, 220 USPQ at 589 (this court reviews the issue of obviousness as one of law on which it must exercise independent judgment—we must be convinced not only that the decision maker engaged in faulty analysis in applying the law to the facts, but also that a correct application of the law to those facts would bring a different result).

The objective evidence of secondary considerations may in any given case be entitled to more or less weight, depending upon its nature and its relationship to the merits of the invention. *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879. Secondary considerations may be the most pertinent, probative, and revealing evidence available to the decision maker in reaching a conclusion on the obviousness/nonobviousness issue. *W.L. Gore*, 721 F.2d at 1555, 220 USPQ at 314.

While it is incumbent upon the decision maker to recognize that evidence of secondary considerations need not be necessarily conclusive on the obviousness/nonobviousness issue; *Fromson*, 755 F.2d at 1557, 225 USPQ at 32, the decision maker must also bear in mind that, under certain circumstances, the evidence of secondary considerations may be particularly strong and entitled to such weight that it may be decisive. For example, in *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575–76, 222 USPQ 744, 747 (Fed. Cir. 1984), the trial court concluded that the claimed invention would have been obvious in light of the teachings of the prior art. But, the trial court had failed to consider the evidence going to secondary considerations in arriving at this conclusion. Holding that the trial court erred as a matter of law by failing to consider the evidence of secondary considerations prior to arriving at its legal conclusion, this court, after considering the teachings of the prior art and the secondary considerations, reversed the decision of the district court.

While the district court in this case found the evidence of commercial success of the chemical sand binders claimed in the '392 and '579 patents impressive, the court found countervailing considerations in the evidence that: (1) after the Milwaukee litigation, *see supra* note 5, one Ashland licensee had effected a downward renegotiation of its royalty payment after initiating a declaratory judgment action against Ashland on the patent claims here in issue; (2) another Ashland licensee went out of the business approximately one year after the grant of the license; (3) industry recognition of the chemical sand binders as claimed in the '392 and '579 patents was directed more towards the marketing of these products rather than the invention thereof; and (4) Dr. Robins, the inventor listed in the '797, '392, and the '579 patents, had not received any recognition from the industry and only a small monetary consideration from Ashland for his role in developing these inventions. On the record before this court, we cannot say that these factual findings made by the district court were clearly erroneous. *See supra* note 13.

The record also reveals, however, that Ashland proffered other evidence of secondary considerations, to wit: (1) affidavits from its industrial customers attesting to the long-felt need satisfied by these chemical sand binders produced by Ashland; (2) the unexpected results, i.e., the "S" or "Z" cure curve, achieved by the '392 and '579 foundry mixes; and (3) the alleged copying by Delta of these chemical sand binders. The opinion rendered by the district court did not discuss these secondary considerations, *see also supra* note 42, and they apparently were not accorded any probative value or entered into the final calculus on the issue of obviousness/nonobviousness. This was error as a matter of law. *Lindemann Maschinenfabrik*, 730 F.2d at 1461, 221 USPQ at 488.

Where the evidence of record is unchallenged as to secondary considerations ignored by the decision maker, this court may, as a matter of law, consider this objective evidence in reviewing the ultimate conclusion of obviousness/nonobviousness entered by the trial court. *Id.*, 221 USPQ at 488. However, where this evidence of record is controverted, as it is in this case, this court will normally remand to the district court for its initial consideration of this evidence. Under the circumstances of this case, however, where we have held that the prior art of record is insufficient to support the legal conclusion of obviousness rendered against the '392 and '579 patents, remand for the district court's consideration of the other evidence going to secondary considerations is not necessary. Nor is it necessary for this court to determine whether a proper consideration of this evidence would have resulted in a different conclusion as to the obviousness of the '392 and '579 patents by the district court. *Union Carbide*, 724 F.2d at 1573, 220 USPQ at 589.

E. CONCLUSION

[1] We have held that the district court committed reversible error in combining the teachings of the Rothrock patent, MEGSON, and MARTIN to reach the conclusion that the subject matter of claim 10 of the '797 patent would have been obvious, and further, that these references, considered individually, would not have supported a conclusion that the subject matter of claim 10 would have been obvious.

We have further held that the district court committed reversible error in combining the teachings of the Rothrock patent, the Japanese patent, and Fraser to conclude that the invention of process claims 1, 2, and 7 of the '797 patent would have been obvious, and that these references, considered singly, would not have supported a conclusion that the invention of these process claims would have been obvious.

We have also held that, inasmuch as one of ordinary skill in the art would not have had knowledge of the Pep resin as claimed in claim 10 of the '797 patent, there was no basis to substitute this resin into the Shepard patent and conclude that the foundry binder inventions of the '392 and '579 patents would have been obvious. Further, as a matter of law there was no basis in either the Shepard patent or the other prior art relied upon by the district court which would have led one skilled in the art to combine the teachings of this prior art with the teachings of the Shepard patent.

Finally, we have held that the district court erred as a matter of law in failing to consider all evidence going to the secondary considerations. And further, that the district court erred by failing to determine if there was the

S.Ct. 2138 (1985); Stratoflex, 713 F.2d at 1539, 218 USPQ at 879.

Ashland argued that the merits of its phenolic urethane foundry binder mixes — Isocure and Pep Set—were due to the characteristics of the phenol-formaldehyde resin, i.e., the Pep resin, substantially as claimed in claim 10 of the '797 patent. *See supra* note 34 and accompanying text. The district court did not make any explicit finding as to the nexus between the merits of the claimed invention and the proferred secondary considerations.

The district court at one point in the opinion stated that the Pep resin is an ingredient in Ashland's Isocure and Pep Set foundry binder mixes. The court stated that the main advantage of these products was the speed and timing of the cure, i.e., the "S" or "Z" cure curve, which increases foundry productivity.

Delta had argued before the district court that Ashland's Isocure and Pep Set Foundry products were not covered by the '579 and '392 patents, respectively, because the Isocure and Pep Set foundry products have only an average of 2.5 phenol rings per molecule, whereas the claims of the '579 and '392 patents require an average of 3 or more phenol rings per molecule. The district court stated that since it had found the patents in suit to be invalid for obviousness under §103, there was no need to determine whether the patents in suit covered Ashland's products. This was error as a matter of law. For secondary considerations to have probative value, the decision maker must determine whether there is a nexus between the merits of the claimed invention and the secondary considerations. *Simmons Fastener Corp.* 739 F.2d at 1575, 222 USPQ at 746; *Stratoflex*, 713 F.2d at 1539, 218 USPQ at 879. Under the circumstances of this case, Ashland's proferred evidence of secondary considerations cannot properly be considered in reaching a conclusion on obviousness/nonobviousness unless the decision maker first determines that these secondary considerations are relevant to the subject matter as claimed. For example, had the decision maker made this determination in this case, and determined that the Isocure and Pep Set produces were not covered by the '579 and '392 patents, respectively, then the secondary considerations would not have had any relevance to the obviousness/nonobviousness determination.

[43] For support for this proposition the district court cited to: *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 283, 189 USPQ 449, 453, *ren'g denied*, 426 U.S. 955 (1976) (1976) ("[P]roducing a desired result in a cheaper and faster way, and enjoying commercial success 'without invention will not make Patentability.' "); *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 153, 87 USPQ 303, 306 (1950), reh'g denied, 340 U.S. 918 (1951) ("But commercial success without invention will not make patentability."); and *Eltra Corp. v. Basic, Inc.*, 599 F.2d 745, 756, 202 USPQ 630, 640 (6th Cir.), *cert. denied*, 444 U.S. 942, (1979) ("Of course, commercial success and satisfaction of long-felt needs are alone not sufficient to establish that the product is the result of invention.").

[44] *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

requisite nexus between the proffered evidence of secondary considerations and the merits of the claimed inventions of the '392 and '579 patents.

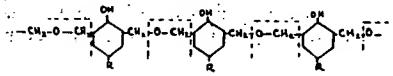
Accordingly, the decision of the district court that claims 1, 2, 7 and 10 of the '797 patent, claims 14 and 19 of the '579 patent, and claim 17 of the '392 patent are invalid is reversed.

The case is remanded for consideration of the infringement issue.

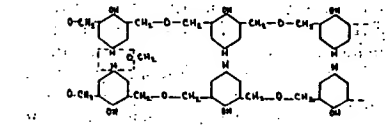
REVERSED AND REMANDED.

APPENDIX
MEGSON, PHENOLIC CHEMISTRY, 29 (Academic Press Inc. 1958)
DETAILED SURVEY

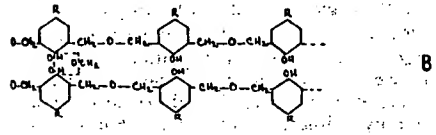
with a dimethylene ether. It is believed, however, that methylene-bridged phenols are important constitutents of resins resulting from the hardening of the alcohols, and if these are formed from the benzyl ethers, then elimination of formaldeyde should be much greater than that actually observed in the second stage of heating.



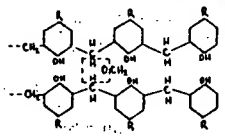
It appears, therefore, that much of the formaldehyde must recombine, and three methods are mentioned by which it can do this. The first involves reaction with nuclear hydrogens to give cross-linked methylene derivatives (A); the second involves reaction with phlenolic hydroxyls to yield cross-linked ethers (B); the third involves reaction with methylene groups (when formed) to give cross-linked compounds of a different type (C).



A



B



C

All these reactions would explain the low evolution of formaldehyde and the high evolution of water during the second stage of hardening.

Court of Appeals, Federal Circuit

KSM Fastening Systems, Inc. v. H.A. Jones Company, Inc., et al.

No. 84-1568
October 29, 1985

PATENTS

1. Contempt of court — New devices (§23.5)

Judgment of contempt against enjoined party for violation of injunction against patent infringement by making, using or selling of modified device may not be upheld without finding that modified device falls within admitted or adjudicated scope of claims and is, therefore, infringement.

2. Contempt of court — In general (§23.1)

Use of contempt proceedings to adjudicate infringement is inappropriate if there are substantial open issues with respect to infringement to be tried, and thus procedural analysis should be used to determine whether contempt proceeding will be allowed, since such standard is more likely to meet due process requirements, in view of usual summary nature of contempt proceedings.

Appeal from District Court for the District of New Jersey, Gerry, J.

Action by KSM Fastening Systems, Inc., against H.A. Jones Company, Inc., and Erico Jones Company, for contempt of court for violation of terms of consent decree entered in patent infringement suit. From judgment for plaintiff, defendant appeals. Vacated and remanded; Newman, Circuit Judge, concurring in part with opinion.

John W. Renner, and Maky, Renner, Otto & Boisselle, both of Cleveland, Ohio (Don W. Bulson, Cleveland, Ohio, on the brief) for appellants.

Charles F. Duffield, and Duffield & Lehrer, both of Cherry Hill, N.J. (Norman E. Lehrer, Cherry Hill, N.J., on the brief) for appellee.

Before Nies, Newman, and Bissell, Circuit Judges.

Nies, Circuit Judge.

This appeal is from an order of the United States District Court for the District of New Jersey (Judge John F. Gerry presiding) holding H.A. Jones Company, Inc. and Erico Jones Company (hereinafter collectively Jones) in civil contempt of court for violation of the terms of a consent decree entered in a patent infringement suit. On April 30, 1979, a predecessor of KSM Fastening Systems, Inc., brought suit against Jones alleging infringement of U.S. Patent No. 3,738,217, which claims a particular hanger assembly or anchor for securing refractory linings to furnace walls (KSM's INSULTWIST), by reason of Jones' manufacture and sale of a device of that type (Jones' THERMAL-LOCK device). Pursuant to a settlement agreement between the parties, which was entered as a consent decree on March 6, 1980, Jones acknowledged the validity of the KSM patent, admitted infringement thereof by its THERMAL-LOCK device, and was enjoined from further infringement.

Jones subsequently put out a modified refractory anchor (ULTRA-LOK I) and on September 22, 1981, KSM moved the court to punish Jones for contempt for violation of the injunction. On July 17, 1984, the court found Jones in contempt by reason of Jones' manufacture and sale of the ULTRA-LOK I device and another model, ULTRA-LOK II, which Jones began marketing in late 1983 or early 1984. This appeal followed.[1]

Under the standard we conclude is appropriate, the judgment must be set aside as a matter of law because of the refusal of the district court to consider whether the Jones ULTRA-LOK devices infringed the claims of the '217 patent. Moreover, the question whether contempt proceedings involving the ULTRA-LOK devices are appropriate must also be reexamined. Therefore, upon remand, the district court is directed to reconsider whether, under the standard set forth herein, infringement with respect to the ULTRA-LOK devices should be tested in contempt proceedings.

I.

Under the Patent Act of 1952, as part of the relief available to a prevailing patent owner, 35 U.S.C. § 283 provides:

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

While the grant of injunctive authority is clearly in discretionary terms, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 865, 221 USPQ 937, 942 (Fed. Cir.), *cert. denied*, 105 S.Ct. 183, 225 USPQ 792 (1984), injunctive relief against an infringer is the norm. *See Smith International, Inc.* v. *Hughes Tool Company*, 718 F.2d 1573, 219 USPQ 686 (Fed. Cir.), *cert. denied*, 104 S.Ct. 493, 220 USPQ 385 (1983).

Having enjoined the infringer, a patent owner who is confronted with another possible infringement by that party in the form of a modified device will very likely seek to invoke the power of the court to punish the adjudged infringer for contempt in violating the court's injunctive order. While a patent owner, in such circumstances, could institute a separate suit to enjoin the modified device, the advantages of proceeding on a motion to hold his adversary in contempt are substantial. The adjudged infringer is already under the jurisdiction of the court and may be summoned to appear to respond on the merits, the contempt motion being merely part of the original action. *Leman* v. *Krentler-Arnold Hinge Last Co.*, 284 U.S. 448, 12 USPQ 306 (1932). Contempt proceedings are generally summary in nature and may be decided by the court on affidavits and exhibits without the formalities of a full trial, although the movant bears the heavy burden of proving violation by clear and convincing evidence. *See* 11 Wright & Miller, *Federal Practice and Procedure: Civil* § 2960 at 591, and cases cited therein; *see also Quinter* v. *Volkswagen of America*, 676 F.2d 969, 974 (3rd Cir. 1982); *A. H. Robins Co., Inc.* v. *Fadely*, 299 F.2d 557, 559 (5th Cir. 1962); *Fox* v. *Capitol Co.*, 96 F.2d 684, 686 (3rd Cir. 1938). If violation is found, the contemnor may be punished by fine (payable to the patent owner) and imprisonment, even in civil contempt. Wright & Miller, *supra*, at 584-85.[2]

[1] The ruling of this court denying a motion to dismiss for lack of a final order is reported at 745 F.2d 630, 223 USPQ 689 (Fed. Cir. 1984).

[2] *See also* Nemmers, Enforcement of Injunctive Orders and Decrees in Patent Cases, 7 Ind. L. Rev., 287 (1973), for analyses of the difference between civil and criminal contempt proceedings and of the

The Court does not conclude that there has been a showing of irreparable injury. I think there was some testimony in respect to competition and sales that could be affected from the plaintiff's vantage point if the defendant is permitted to use and copy this product; but if the plaintiff is not entitled to trademark protection, then the marketplace will decide the extent to which the parties will prevail.

The plaintiff may prevail. It may require a more aggressive sales or promotion or whatever, but that is the place where the degree of sales and market success will be measured, not by the denial of the preliminary injunction.

The Court does not believe the plaintiff has shown the existence of irreparable injury.

As far as the public interest is concerned, if safety is a factor here — safety was mentioned several times — if safety is a factor here, that is certainly something that I suppose should be advanced as a plus for the product, that it is more safe than others, in an expectation of achieving a greater share of the marketplace, but there is no evidence that products other than those of the plaintiff's pose any danger to the public or to the community. There is no evidence that they violate any particular fire code. If they do, the remedy would seem to be through the enforcement of those codes.

As far as hardship to the parties is concerned, the Court believes no hardship recognizable in the form not protected by a preliminary injunction exists.

As far as the defendant is concerned, there has been some testimony about the loss of costs relative to molds, inventory, and the like. That testimony, I think, would not cause the Court to say that the hardship is so compelling on defendant that to grant the preliminary injunction would visit hardship recognizable on the preliminary injunction level on the defendant.

The defendant is presumably a substantial company with substantial assets, as has been represented to the Court, and the costs that were advanced, as suggested here as being advanced to develop its product, while they were substantial, would not in my view be the type of hardship that would cause the Court to act or hesitate to act in the face of those figures. So I don't think I am moved by that. That's not the reason to deny the preliminary injunction.

The real reason and the primary reason and the principal reason and hence the only legal reason is the features having to do with its eligibility for trademark protection under the doctrines I have discussed, having to do with the functionality, arbitrariness and the like, lack of secondary meaning and the like.

There is no evidence that the Court believes here of passing off that would cause the Court to re-examine its expectation that its final ruling would be the denial of a preliminary injunction.

I think those cases that speak of passing off suggest a real pattern of deception or act of deception and intent to cause a prospective purchaser to believe that it is buying the other product, not a product like the others but indeed the other product.

There has been some suggestion that the shipping box used here is very similar, and it is, but the shipping boxes are relatively standard, straightforward shipping boxes. The carton is brown corrugated paper in the form of a rectangle, having red printing on it like many hundreds or thousands of other boxes.

More than that, there is evidence here that the name of the plaintiff is on the side of the box, and there is no name on the side of the defendant's. That in itself wouldn't support passing off, it would seem to the Court.

Furthermore, inside the carton there is testimony of a product sheet with the defendant's logo on it and the defendant's description. Again, the persons who opened these boxes and use them have to exercise at least minimal diligence before they can be deceived. While they don't have to have the intelligence or concern of a custom's inspector, they have to be at least reasonably alert and read what is before them, and if they do that, they can't believe, evidence suggests, that there is any sort of an attempt to pass off.

Furthermore, there is evidence that when these objects are delivered by the defendants even in these boxes, they are delivered with other items that the company sells presumably to the same customers, and presumably the same salesmen who take orders for these products take orders for other products, candles and the like.

So that while the hearing may finally show that there was deception and an intent to pass off the defendant's product as really being that of the plaintiff, at this juncture there is insufficient evidence for the Court to consider allowing relief to that extent.

I might say the cases that have been furnished by the parties have been useful and helpful, and I think they are the cases the Court has relied upon.

There has been considerable reference to the Dallas Cowboys case, which I think is a case that helps the Court in this regard and I think it is consistent with the Court's ruling.

Several of the other cases that are in the briefs, I think the Third Circuit cases are especially helpful, but we have some others as well. The Ideal Tool Corporation versus Warner Tool Manufacturing Corporation, a Third Circuit case at 685 Fed2d 78, a case out of New Jersey, furnished the Court with some help.

SKF, Judge Gibbons' decision in SKF v. Primo Pharmaceutical, was helpful, and especially helpful was Judge Sloviter's decision in King Corporation v. Paraflex. I think she stressed the doctrine of aesthetic functionality in a way that helps us in this case.

For those reasons the Court concludes that the motion by the plaintiffs for preliminary injunction is denied, and the case will proceed through its normal course of litigation, and of course the Court will develop a course of discovery upon application by the parties under Federal Rules of Civil Procedure.

Hopefully, the Court can list this matter for an early disposition. The Court would like to think in terms of concluding the discovery by the first of February or sooner; the filing of pretrial memorandum by February 15th, with the case ready for ultimate final hearing any time after February 15th, as the Court permits it.

As the parties know, the testimony and evidence offered at a preliminary injunction hearing would be combined with and collapsed into a final hearing, so there is no need to repeat or go over that testimony again.

With that the Court will declare that this ruling is its findings of fact and conclusions of law, and the Court will conclude by saying that the Court does have jurisdiction over the parties based upon the diversity of citizenship of the parties, and the amount in controversy, exclusive of costs, exceeds $10,000.

The Court so finds. So ordered.

On these exhibits, I would like you to advise Miss Coe within the next ten days as to the disposition of these exhibits. It's difficult for us to maintain them here and we can't assure really their security. There is no need to worry about that for a week or so but call Miss Coe and advise her of the disposition of the exhibits.

So ordered.

U.S. International Trade Commission

In re Certain Limited-Charge Cell Culture Microcarriers

No. 337-TA-129

Decided Nov. 18, 1983

UNFAIR COMPETITION

1. Importation restrained under Tariff Act (§68.60)

19 CFR 210.54 governs petitions for review of initial determinations before U.S. International Trade Commission.

PATENTS

2. Pleading and practice in courts — Burden of proof — Validity (§53.138)

Presumption from patent grant — In general (§55.1)

Under 35 USC 282, patents are presumed to be valid; burden of proving invalidity is on party asserting it.

3. Claims — In general (§20.01)

Patent claim is definition of patented invention.

4. Claims — Indefinite (§20.55)

35 USC 112, second paragraph, requires patent specification to conclude with claims particularly pointing out and distinctly claiming invention; shorthand for this requirement is "definiteness"; it is requirement that claims be free from ambiguity so that public may determine with reasonable certainty whether or not they infringe claims; claim is definite if scope of subject matter embraced by claim is clear, and if patentee has not otherwise indicated that he intends claim to be of different scope.

5. Amendments to patent application — In general (§13.1)

Specification — Sufficiency of disclosure (§62.7)

35 USC 112, first paragraph, provides that specification shall contain written description of invention, meaning claimed invention; original claims constitute their own description; thus, requirement is important only when claims have been amended during prosecution of application, being requirement that new definition of invention in amended claim be based on description originally in specification; requirement assures that newly defined invention is entitled to original filing date of application.

6. Specification — Sufficiency of disclosure (§62.7)

Enablement requirement set out in first paragraph of 35 USC 112 requires that specification contain sufficient information to enable person skilled in relevant art to make and use invention.

7. Specification — Sufficiency of disclosure (§62.7)

Fact that experimentation may be complex does not necessarily make it undue, if art typically engages in such experimentation.

8. Patentability — Invention — In general (§51.501)

Even if claimed invention is not identically disclosed in prior art, 35 USC 103 provides that it is not patentable if differences between subject matter sought to be patented and prior art are such that subject matter as whole would have been obvious at time invention was made to person having ordinary skill in art to which subject matter pertains.

9. Patentability — Invention — In general (§51.501)

Scope and content of prior art must be examined and differences between prior art and claims ascertained.

10. Patentability — Anticipation — Publications — What is publication (§51.2277)

Document may be deemed printed publication upon satisfactory showing that it has been disseminated or otherwise made available to extent that persons interested and of ordinary skill in subject matter or art, exercising reasonable diligence, can locate it; dissemination of copies to at least 6 persons without restrictions is publication when there were between 50 and 500 persons interested and of ordinary skill who knew of existence of paper and were informed of its contents by oral presentation.

UNFAIR COMPETITION

11. Importation restrained under Tariff Act (§68.60)

There must exist industry, efficiently and economically operated, in U.S., in order for ITC to find Section 337 violation.

PATENTS

12. Applications for patent — Divisional (§15.5)

Facts that one patent is division of other patent means that two patents are directed to independent and distinct inventions as provided by 35 USC 121, under which divisions may be required.

UNFAIR COMPETITION

13. Importation restrained under Tariff Act (§68.60)

Complainants, to prevail under Section 337, must prove not only that respondents committed unfair practices alleged, but also that respondent's unfair practices have effect or tendency to substantially injure domestic industry; Commission practice emphasizes separate nature of injury and unfair practice requirement; each element requires independent proof; establishment of patent infringement does not release complainants from burden of establishing substantial injury, or of showing requisite causal connection between imports and injury.

Particular patents — Cell Cultures

4,189,534, Levine, Thilly, Wang, and Wong, Cell Culture Microcarriers, invalid, but if valid, not infringed for 1930 Tariff Act Section 337 purposes.

4,293,654, Levine, Thilly, Wang, and Wong, Cell Culture Microcarriers, invalid, but if valid, not infringed for 1930 Tariff Act Section 337 purposes.

U.S. International Trade Commission proceeding No. 337-TA-129, on behalf of Flow General, Inc., Flow Laboratories, Inc., and the Massachusetts Institute of Technology, for exclusion of certain limited-charge cell culture microcarriers, in which AB Fortia, Pharmacia AB, Pharmacia Fine Chemicals AB, and Pharmacia, Inc., were designated as respondents. Investigation terminated.

David Brook, and Hamilton, Brook, Smith & Reynolds, both of Lexington, Mass., and Harvey Kaye, and Spencer & Kaye, both of Washington, D.C., for complainants.

Marc C. Gross, James A. Quinton, and Hubbell, Cohen, Steifel & Gross, all of New York, N.Y., and Leslie A. Glick, and Adduci, Binan & Mastriani, both of Washington, D.C., for respondents.

Juan Cockburn and Wayne Herrington, ITC investigative staff.

Before Eckes, Chairman, and Stern, Haggart, and Lodwick, Commissioners.

Views of the Commission [1]

The following opinion reflects the Commission's determination on review of the initial determination (ID) of the administrative law judge (ALJ) in Certain Limited-Charge Cell Culture Microcarriers, Inv. No. 337-TA-129.[2] The ALJ issued his ID on June 6, 1983, in which he determined that there was no violation of section 337 of the Tariff Act of 1930[3] on the basis that: (1) the patents involved are invalid and (2) respondents have not unfairly refused to sell sieved beads for making microcarriers. Patent infringement, unauthorized manufacture abroad in accordance with the process claims of a U.S. patent, and the refusal to sell sieved beads were the only alleged unfair practices remaining in the investigation at the time the ALJ issued his ID. The ALJ found all the other elements of a violation of section 337 to exist.

We agree with the ALJ that there is no violation of section 337. However, we have also determined to modify the ID, as discussed below.

Procedural History

On July 19, 1982, Flow General, Inc. (Flow General), Flow Laboratories, Inc. (Flow), and the Massachusetts Institute of Technology (MIT) filed a complaint with the Commission under section 337 of the Tariff Act of 1930. A supplement to the complaint was filed on August 3, 1982.

On the basis of that complaint, as supplemented, the Commission instituted this investigation on August 19, 1982.[4] The notice of investigation was subsequently amended, so that as the investigation reached the ALJ for decision, the amended notice of investigation defined its scope as the determination of whether there is a violation of section 337 in the importation of certain limited-charge cell culture microcarriers into the United States, or in their sale, by reason of alleged:

(1) refusal to sell sieved beads;

(2) direct infringement of the claims of U.S. Letters Patent 4,189,534 (the '534 patent) and U.S. Letters Patent 4,293,654 (the '654 patent);

(3) contributory infringement and induced infringement of the claims of said patents; or

(4) unauthorized manufacture abroad in accordance with the process claims of U.S. Letters Patent 4,293,654,

the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States.[5], [6]

The following four parties were named respondents in the notice of investigation: AB Fortia, Pharmacia AB, and Pharmacia Fine Chemicals AB, all of Uppsala, Sweden, and Pharmacia, Inc., of Piscataway, New Jersey.

[1] After an evidentiary hearing, the ALJ issued the ID on June 6, 1983, finding that there is no violation of section 337. Both complainants and respondents petitioned for review of the ID.[7]

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[1] The following abbreviations are used in this opinion:
ALJ = Administrative Law Judge; ID = ALJ's Initial Determination:
CX = complainants' exhibit; RX = respondents' exhibit;
TR = transcript of evidentiary hearing before ALJ;
CTR = transcript of Commission hearing on ALJ's initial determination on violation and also on remedy, public interest, and bonding;
CHB = complainants' prehearing brief for the Commission hearing;
RHB = respondents' prehearing brief for the Commission hearing;
CPB = complainants' posthearing brief for the Commission hearing;
RPB = respondents' posthearing brief for the Commission hearing.

[2] The Commission's review was pursuant to Rule 210.56(c), 19 CFR § 210.56(c).

[3] 19 U.S.C. §1337.

[4] 47 Fed. Reg. 37312 (August 25, 1982).

[5] The amendment of the notice of investigation was accomplished by a joint motion of the parties, filed March 8, 1983, to amend the complaint and notice of investigation by withdrawing as alleged unfair methods of competition and unfair acts: (1) misappropriation of trade secrets; (2) false and deceptive advertising; and (3) false and disparaging comments about complainants. By Order No. 28, issued on March 14, 1983, the ALJ filed an initial determination pursuant to Rule 210.53(c), 19 CFR §210.53(c), granting that joint motion. On April 8, 1983, the Commission issued a notice that it would not review that initial determination. 48 Fed Reg. 15966 (April 13, 1983).

[6] The complaint had alleged "misrepresentation to prevent issuance of patents." The Commission did not find it appropriate to include this count in its notice of investigation; the complainants concurred in the Commission's action. 47 Fed. Reg. 37312 (August 25, 1982); See, Memorandum of the Unfair Import Investigations Division to the Commission, UIID-F-241 (August 10, 1982).

[7] Rule 210.54, 19 CFR §210.54, governs petitions for review. That rule provides the following standards for granting such petitions;

(A) A finding or conclusion of material fact [in the ID] is clearly erroneous;

On July 14, 1983, the Commission issued a notice that it had determined to review the following portions of the ID:[8]

1. Validity of involved U.S. Letters Patent Nos. 4,189,534 and 4,293,654 (the patents) under 35 U.S.C. §112, 35 U.S.C. §102 (prior art Sephadex A-50 product only), and 35 U.S.C. §103.
2. Infringement of the patents by respondents' CYTODEX 3 product.
3. Whether there is an "industry * * * in the United States," within the meaning of section 337.
4. Whether the importation or sale of respondents' CYTODEX products which are found to be involved with unfair practices have the effect or tendency to destroy or substantially injure such an industry.

On September 15, 1983, the Commission held a hearing on those portions of the ID it had determined to review and on relief, the public interest, and bonding.

Parties

Complainant MIT is a Massachusetts corporation and a research and educational institution having its principal place of business at 77 Massachusetts Avenue, Cambridge, Massachusetts 02137. MIT is the owner by assignment of the '534 patent and the '654 patent.

Complainant Flow General is a Delaware corporation having its principal place of business at 7655 Old Springhouse Road, McLean, Virginia 22102. Flow General is engaged in the manufacture and sale of products for cell culturing, microtitration, and clinical diagnostic assays. Flow General is the exclusive licensee of MIT under the '534 and '654 patents.

Complainant Flow is a Maryland corporation and a wholly owned subsidiary of Flow General. Its principal place of business is also 7655 Old Springhouse Road, McLean, Virginia 22102. Flow was established in 1961 to manufacture products for cell culturing, including media and sera required for cell growth.

Respondent AB Fortia is a Swedish corporation having its principal place of business at Uppsala, Sweden, (018) 163000. AB Fortia is the parent corporation of respondents Pharmacia Fine Chemicals AB and Pharmacia, Inc.

Respondent Pharmacia AB is a Swedish corporation having its principal place of business at Uppsala, Sweden, (018) 163000. Pharmacia AB is affiliated with respondents Pharmacia Fine Chemicals AB and Pharmacia, Inc.

Respondent Pharmacia Fine Chemicals AB (Pharmacia) is a Swedish corporation and a subsidiary of AB Fortia, having its principal place of business at Uppsala, Sweden, (018) 163000.

Respondent Pharmacia, Inc., is a New Jersey corporation and a subsidiary of AB Fortia, having its principal place of business at 800 Centennial Avenue, Piscataway, New Jersey 08854.

Technology Involved [9]

This investigation involves complex subject matter; thus, the issues raised in this investigation may be more clearly understood by an overview of the technology involved. The involved technology is the large-scale culturing of mammalian cells. More particularly, it is the large-scale culturing of mammalian cells on microscopic beads called microcarriers.

Mammalian cells synthesize many proteins which have experimental, clinical, and perhaps commercial value.[10] In many cases, the best or only source of these proteins is by culturing the mammalian cells known to produce them.[11] Techniques for culturing mammalian cells on a small, laboratory scale have been known for some time; the problem has been in moving from small-scale laboratory culturing to large-scale culturing. Culturing mammalian cells on a large scale is much more difficult than culturing bacteria, yeasts, or molds because of the fragile and complex nature of mammalian cells, which have stringent nutritional and environmental requirements. Among these environmental requirements is the requirement for a solid surface or substrate on which to grow; only a few unusual mammalian cells will grow in suspension. Thus, the majority of mammalian cells are "anchorage-dependent."

A number of laboratory vessels are suitable as substrates. The most effective and widely used vessel is the roller bottle, a cylindrical vessel partially filled with medium and continuously rotated about its long horizontal axis. Cells attach themselves to the inner surface of the cylinder, and the slow rotation exposes them alternately to the liquid medium and the air.

However, roller bottles cannot provide a sufficiently large surface area to volume ratio for practical large-scale culturing. Various means have been devised to increase the surface area to volume ratio, such as growing the cells on spongy polymers, on arrays of thin tubing or hollow fibers, on stacks of thin plates, or on microscopically small beads known as microcarriers.

The use of microcarriers as a substrate for culturing mammalian cells was developed in 1967 by Anton L. van Wezel, of the Dutch National Institute for Public Health. Dr. van Wezel used commercially available anion exchange resin beads marketed by Pharmacia under the trade name DEAE-Sephadex A-50 for his microcarriers. Various microcarriers and microcarrier techniques have since been developed. In general, the technique involves suspending the microcarriers in a nutrient medium. An inoculum of anchorage-dependent cells is introduced into the medium. The cells attach to the beads, grow, and multiply.

The use of microcarriers has the advantage of closely approximating suspension culture, but there are some problems. Collisions between beads can injure cells, and such collisions become more frequent with high bead density and the agitation characteristic of suspension culture. Cell growth over the large surface to volume area of the microcarrier beads may also result in rapid nutrient depletion and build-up of toxic waste products.

Patents Involved [12]

1. The '534 patent

United States Patent No. 4,189,534, entitled "Cell Culture Microcarriers," was issued February 19, 1980, to David W. Levine, William G. Thilly, Daniel I. C. Wang, and Jason S. Wong. The patent was based on application Serial No. 842,696, filed October 17, 1977, which was a continuation-in-part of application Serial No. 740,993, filed November 11, 1976. The '534 patent is assigned to complainant MIT. The United States Government has rights under this patent pursuant to NSF Grant No. BMS 7405676A01 and NIEHS Grant No. TO1 ES 00063.

The '534 patent contains 20 claims, of which claims 1, 4, 7, 10, 12, 13, 19, and 20 are considered representative claims.[13] It claims a method for using the microcarriers claimed in the '654 patent as a substrate for growing anchorage-dependent cells and recovering cell by-products from such cells.

2. The '654 patent

United States Patent No. 4,293,654, entitled "Cell Culture Microcarriers," was issued on October 6, 1981, to David W. Levine, William G. Thilly, Daniel I. C. Wang, and Jason S. Wong. The patent was based on application Serial No. 54,319, filed July 2, 1979, as a division of application Serial No. 842,696 (now the '534 patent), filed October 17, 1977, which was a continuation-in-part of application Serial No. 740,993, filed November 11, 1976. The '654 patent is assigned to complainant MIT. The United States Government has rights under this patent pursuant to NSF Grant No. BMS 7405676A01 and NIEHS Grant No. TO1ES 00063.

The '654 patent contains 9 claims, of which claims 1, 2, 4, and 7 are considered to be representative claims.[14] It claims "cell culture microcarriers" having a "charge capacity" of 0.1 to 4.5 milliequivalents (meq) per gram "of dry, untreated microcarriers."[15] The microcarriers are composed of beads "formed from polymers containing pendant hydroxyl groups," to which "positively charged amino groups" have been attached to provide the "charge capacity."[16] These beads are generally porous. The preferred bead is one of cross-linked dextran, and the preferred charge carrying group is diethylaminoethyl (DEAE). Thus, the preferred microcarrier is a porous, cross-linked dextran bead to which DEAE groups have been attached to provide the requisite "charge capacity."[17] The '654 patent also claims a method for producing the cell culture microcarriers it claims.

(B) A legal conclusion is erroneous, without governing precedent, rule or law, or constitutes an abuse of discretion; or

(C) The determination is one affecting Commission policy.

[8] 48 Fed. Reg. 32878 (July 19, 1983), as amended by 48 Fed. Reg. 36011 (August 8, 1983).

[9] A more detailed discussion of the technology involved may be found in Feder and Tolbert, "The Large-Scale Cultivation of Mammalian Cells," Scientific American (January 1983); CX-219.

[10] Among these proteins is interferon, which is known to inhibit viral infection.

[11] A typical mammalian cell culture begins with a mammalian tissue which is dissociated into individual cells or groups of cells to form a mixture of cells known as an inoculum. The inoculum is introduced into an appropriate liquid growth medium, which ordinarily includes serum to provide components not yet identified, but which have been shown to be essential for cell growth. The pH, temperature, oxygen and carbon dioxide levels and osmotic pressure of the medium must be carefully controlled.

[12] The '534 patent (CX-1) and the '654 patent (CX-2) are reproduced in the Appendix.

[13] TR at 76 (Prehearing Conference).

[14] TR at 76 (Prehearing Conference).

[15] Claim 1.

[16] Col. 5, l. 59 - col. 6, l. 2.

[17] Claimed in claim 3.

3. Terminology of the patents

To understand the claims of both patents more clearly, it is necessary to discuss the meaning of the terminology used in the claims, particularly the terms "cell culture microcarriers," "charge capacity," and "dry, untreated microcarriers." [18]

The term "cell culture microcarriers" is defined in the specification of each patent as "small, discrete particles suitable for cell attachment and growth." [19]

The term "charge capacity," also referred to in some of the claims as "exchange capacity," is terminology used to characterize ion exchangers. The reason for this is that the claimed invention is, at least in its preferred embodiment, said to be an improvement over a prior art material, DEAE-Sephadex A-50, a well-known ion exchange bead, made by respondents and used, among other things, as a microcarrier.[20]

The charge capacity of an ion exchanger is a quantitative measure of its ability to take up exchangeable counter ions. The capacity may be expressed as total capacity or available capacity. The total capacity is the amount of charged and potentially charged groups per gram of dry ion exchanger; it is essentially a measure of the number of charged groups dispersed throughout the matrix of the ion exchange bead. The available capacity is the actual capacity obtainable under specified experimental conditions. It is dependent on the accessibility of functional groups, concentration and ionic strength of the surrounding liquid medium, the nature of the counter ions, and the selectivity of the functional groups towards them. In the claims, charge capacity refers to total charge capacity.

The term "dry, untreated microcarriers" refers to the polymer beads prior to treatment to attach the positive charge-carrying groups. In the case of the preferred embodiment these would be cross-linked dextran beads such as commercially available Sephadex G-50 made by respondents.

Products

The products involved in this investigation are limited-charge cell culture microcarriers, which generally refers to cell culture microcarriers having a charge capacity less than that of DEAE-Sephadex A-50.

Complainants' microcarriers are sold under the mark SUPERBEAD. They are prepared from an uncharged cross-linked dextran product, Sephadex G-50, manufactured by respondents, to which are attached positively charged DEAE groups; it is not disputed that SUPERBEAD microcarriers come within the claims of the '654 patent. All of complainants' SUPERBEAD microcarriers are manufactured in Scotland, by Flow Laboratories, Ltd.,[21] and are marked "Made in U.K." [22]

Respondents import and sell three microcarrier products as follows: CYTODEX 1, a cross-linked dextran bead having DEAE charge groups attached throughout the bead; (b) CYTODEX 2, a cross-linked dextran bead having N, N, N-trimethyl-2-hydroxyaminopropyl (THAP) charge groups attached only at the outer surface of the bead; and (c) CYTODEX 3, a dextran bead coated with denatured collagen.

Patent Validity [23]

[2] Under 35 U.S.C. §282, patents are presumed to be valid. The burden of proving invalidity is on respondents. The ALJ found that both patents are invalid for: (1) indefiniteness under 35 U.S.C. §112, second paragraph; (2) failure to meet the description requirement under 35 U.S.C. §112, first paragraph; (3) failure to meet the enablement requirement under 35 U.S.C. §112, first paragraph; and (4) obviousness of the claimed inventions under 35 U.S.C. §103. The ALJ also found the '654 patent invalid for anticipation of the claimed invention under 35 U.S.C. §102. We will address each of these questions separately.

1. Indefiniteness (35 U.S.C. §112, second paragraph) [24]

The claims define the exchange or charge capacity of the claimed microcarriers in terms of milliequivalents per gram of "dry, untreated microcarriers," i.e., in terms of the weight of the polymer beads used as the starting material for making the claimed microcarriers. The parties refer to this method of defining the charge capacity as the "MIT basis." Respondents measure the charge capacity of their CYTODEX microcarriers in terms of the weight of the final (treated) microcarrier product and allege that this is the conventional method for expressing charge capacity. The parties refer to respondents' method of defining the charge capacity as the "Pharamcia basis" or the "conventional basis." The ALJ found that the claims were indefinite because of the absence of any disclosure in the patents which relates the "MIT basis" to the "conventional basis," making it difficult, if not impossible, for members of the public to determine whether their microcarriers infringe the claims or not. The ALJ noted that the parties now agree on a conversion formula [25] relating the "MIT basis" to the "conventional basis," but found that there is uncertainty as to the MW factor in the formula, which calls for the molecular weight of the charge-carrying moiety in its charged state, i.e., as attached to the polymer bead to impart a positive charge. He based his finding on evidence of instances where certain of the inventors had used a molecular weight for the charge-carrying DEAE moiety of the preferred embodiment which did not include the molecular weight of the chloride counter ion associated with it or included an additional chloride counter ion.

[3,4] We determine that the claims are not invalid for indefiniteness under 35 U.S.C. §112, second paragraph. A patent claim is a definition of the patented invention. The statute, 35 U.S.C. §112, second paragraph, requires the patent specification to conclude with claims "particularly pointing out and distinctly claiming" the invention. The shorthand for this requirement is "definiteness." It is a requirement that claims be free from ambiguity so that the public may determine with reasonable certainty whether or not they infringe the claims. If the scope of the subject matter embraced by a claim is clear, and if the patentee has not otherwise indicated that he intends the claim to be of a different scope, then the claim is definite.[26]

There is no serious dispute that the subject matter embraced by the claims here is clear, and there is no indication that the scope of the claims is intended to be different.[27] The dispute is whether, as a practical matter, members of the public may have difficulty determining whether or not they infringe these claims because they might have difficulty ascertaining the appropriate molecular weight to be used in the conversion formula. We do not feel that this is a question of definiteness at all. However, assuming it to be a question of definiteness, respondents have failed to carry their burden. In the first place, it is clear that manufacturers can determine whether or not they infringe the claims without the necessity for any conversion formula since they can determine charge capacity directly on the "MIT basis" by weighing out the dry polymer beads prior to treatment to attach the charge-carrying moiety. This method is described in Example 1 of both patents. While this method is limited to manufacturers, such as respondents, there is no reason why it should not be sufficient. The parties agree there is an entire class of claims,

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[18] To the extent that there remains any dispute as to the meaning of these terms, this discussion constitutes the Commission's disposition thereof.

[19] '534 patent, col. 4, 11. 30-33; '654 patent, col. 4, 11. 32-35.

[20] An ion exchanger is an insoluble material containing chemically bound charged groups and mobile counter ions. The counter ion may be reversibly exchanged with other ions of the same charge without any changes of the insoluble matrix. If the matrix carries positive groups the counter ions will be negative. Such an ion exchanger will exchange negative ions and is therefore termed an anion exchanger. In the same way, if the matrix carries negative groups the counter ions will be positive. Since the positive ions are exchangeable, the term cation exchanger is used. DEAE-Sephadex A-50 is an anion exchanger. The presence of charged groups is a fundamental property of an ion exchanger. The total number of groups and their accessibility determine the capacity. See, Sephadex Ion Exchangers, A Guide to Ion Exchange Chromatography, RX-12, admitted to be prior art. CHB 14. See also, CHB, App. B. (Glossary of Technical Terms).

[21] See p. 37 et seq.; infra.

[22] TR at 1071.

[23] Except where indicated, the issues and arguments relate to all claims in issue in the '654 and '534 patents; however, the arguments have been largely framed in terms of claim 1 of the '654 patent. Complainants appear to let the validity of the '534 patent rise or fall with the '654 patent. See also, TR at 960.

[24] ID at 12-18, 98-109.

[25] The conversion formula is:

$$CC_{MIT} = \frac{CC_{ph}}{1-[CC_{ph}\ (MW)\quad (0.00)]}$$

Wherein:

CC_{MIT} = Charge capacity on MIT basis, meq/gm dry *untreated* microcarrier.

CC_{ph} = charge capacity on Pharmacia or conventional basis, meq/gm dry *treated* microcarrier.

MW = Molecular weight of charge-supplying group in its charged state, i.e., as attached to the microcarrier bead. RHB App.; CHB App. C.

[26] In re Borkowski, 422 F.2d 904, 909; 164 USPQ 642; 645 (CCPA 1970).

[27] Respondents argue in their posthearing brief that "there has never been a satisfactory explanation of what 'per gram of untreated microcarrier' means." RPB (Answers to Commission Questions) at 17. However, as noted above, it is manifest from the patents that this term refers to the dry, polymer (e.g., dextran) beads before treatment to attach the charge-carrying moiety. See p. 10, supra.

referred to as product-by-process claims, in which the claimed product is defined in terms of a process for making it.[28] They also agree that such claims are not invalid for indefiniteness merely because only a manufacturer can determine infringement.[29] Respondents have cited no authority why the present claims should be treated differently from product-by-process claims.[30]

In the second place, it has not been established that the relevant segment of the public would not be able to convert from the "conventional basis" to the "MIT basis." There is no dispute that the conversion can be made, and the parties agree on what the conversion formula is.[31] The only dispute has to do with the alleged uncertainty of the molecular weight (MW) of the charge-carrying moiety, which is a factor in the conversion formula. The evidence for this uncertainty, however, does not relate to an uncertainty of what the molecular weight of the charge-carrying moiety is, but whether the molecular weight factor in the formula should include the molecular weight of the counter ion associated with the charge-carrying moiety. The evidence showed the use of three different molecular weights for the DEAE moiety, the preferred charge-carrying moiety: 100, 135, and 172 (Approx.). These are appropriate molecular weights depending on whether the molecular weight of the chloride counter ion associated with the DEAE moiety is included as part of the molecular weight factor in the formula and whether there are one or two chloride counter ions associated with each attached DEAE moiety. The parties agree that the molecular weight of the chloride counter ion should be included, and that there is only one of these associated with each attached DEAE moiety. As the ALJ found, it is a simple matter to determine the appropriate molecular weight to use in the formula; once this question is resolved, one simply adds the appropriate atomic weights obtained from a Periodic Table of the Elements. The parties substantially agree on the molecular weight factor to be used for the preferred embodiment. Respondents have not established that it is not within the skill of persons in the art to determine the proper molecular weight for use in the conversion formula whenever it becomes necessary to do so. When the question became important, as it did in the context of this case, the proper conclusion was readily drawn.

2. Description requirement (35 U.S.C. §112, first paragraph) [32]

The ALJ found that the description requirement is not met for three different reasons. First, the ALJ found that the patents contain no disclosure of how to determine whether microcarriers whose charge capacity is characterized on the "conventional basis" are within the claims of the patents, which specify charge capacity on the "MIT basis." This is the same ground on which the ALJ made his finding of indefiniteness.[33]

Second, the ALJ found that the disclosure of the patents is inadequate to permit those skilled in the art to determine whether microcarriers characterized on the "MIT basis" are within the scope of the claims. The ALJ found this inadequacy to be due to the failure of the patent disclosures to take into account the following "errors":

1) a 7% error attributable to moisture retained in the untreated beads even after conventional drying to constant weight;
2) a 2% error attributable to loss of free dextran during treatment of the beads to attach the charge-carrying moiety;
3) a 5% error attributable to degradation of the cross-linked dextran beads during treatment of the beads to attach the charge-carrying moiety;
4) a 2% error attributable to error in determining the correct molecular weight of the attached charge-carrying moiety.[34]

[28] CTR at 80-82; CTR at 111-112 (as corrected).

[29] CTR at 80-82; CTR at 112 (as corrected). See, In re Hughes, 496 F.2d 1216; 182 USPQ 106 (CCPA 1974).

[30] They appear to agree that the present claims should not be treated differently. CTR at 12. However, they argue in their posthearing brief that "it is unlikely that an ion exchange manufacturer would perform special tests during its manufacture for a small customer for the small amounts used in cell culture and attempt to determine whether its product is within the MIT definition of charge capacity." RPB (Answers to Commission Questions) at 15. The point, however, is not whether they would perform such a test, but whether such a test is available, which it is. Respondents also argue that even manufacturers would be hampered by certain so-called "error factors." RPB (Answers to Commission Questions) at 16. As discussed infra, p. 17, these "error factors" have nothing to do with the direct determination of charge capacity on the MIT basis as set out in Example 1 of the patents.

[31] See note 25, supra.

[32] ID at 12-18, 109-124.

[33] See p. 11, supra.

[34] Using these "error factors," the ALJ "corrected" the claimed charge capacity range in the patents from 0.1-4.5 meg/g of dry, untreated microcarriers to 0.12-5.36 meg/g, which he found resulted in anticipation of the claimed invention by the prior art DEAE-Sephadex A-50 microcarriers. *See* the discussion of novelty, *infra*, p. 20.

Third, the ALJ found that the specification of each of the patents contains an "alternative definition" of the claimed invention which purports to define the charge capacity of the microcarriers in hydrated form on the "conventional basis." The ALJ found that when the charge capacity of DEAE-Sephadex A-50 was adjusted to account for the hydration, it came within this "alternative definition." Pointing to the fact that the "alternative definition" is different from the definition of the invention in the claims, the ALJ found this "compounds the confusion" he had already found to exist with respect to the conversion formula.

[5] We find that the patents are not invalid for failure to meet the description requirement. The first paragraph of section 112 provides that the "specification shall contain a written description of the invention * * *," meaning the claimed invention. Original claims constitute their own description.[35] Thus, the requirement is important only when the claims have been amended during prosecution of the application at the Patent and Trademark Office (PTO), being a requirement that the new definition of the invention in an amended claim be based on a description originally in the specification. The requirement assures that the newly defined invention is entitled to the original filing date of the application.[36] The invention defined in the claims is clearly described in the specification. The specification as originally filed clearly conveys to those skilled in the art the information that the inventors have invented the specific subject matter of the claims. This is sufficient.[37]

The ALJ's first reason clearly does not relate to whether the claims are supported by the original specification and in any event proceeds from an incorrect premise, i.e., that it would not be possible to determine infringement of such claims.[38]

As to the second reason, it also does not relate to whether the claims are supported by the original specification and in any event proceeds from an incorrect premise, since the "errors" referred to by the ALJ have nothing to do with the direct determination of charge capacity on the "MIT basis" as set forth in Example 1 of the patents. The 7% error attributable to the retained moisture after drying to constant weight is in fact included in the weight of the dry, untreated microcarriers in Example 1, by definition of the word "dry." [39] The 2% error attributable to washing away of free dextran and the 5% error attributable to degradation during treatment to attach the charge-carrying moiety obviously have nothing to do with the determination of the weight of the untreated beads and thus can have nothing to do with the direct determination of charge capacity on the "MIT basis." The 2% error attributable to the determination of the molecular weight of the charge-carrying moiety has nothing to do with the determination of the weight of the untreated dextran beads in Example 1 of the patents, because at that point the beads, being untreated, do not have the charge-carrying moiety attached to them. In addition, the evidence relied on to find that these errors exist was the testimony of an employee of respondents who, though an expert in his field, admitted he had not carried out any examples in the patents [40] and whose testimony consisted essentially of estimates. Such testimony, in our view, should not be given great weight.

As to the third reason, the existence of an "alternative definition" does not detract from the fact that the claims are clearly supported by the original specification. In any event, there can be no confusing the description of the claimed invention with the "alternative definition," since the former clearly expresses charge capacity on the "MIT basis" and the latter clearly does not.[41]

3. Enablement requirement (35 U.S.C. §112, first paragraph) [42]

The ALJ found that the specifications do not teach those of ordinary skill in the art how to use those claimed microcarriers having a charge capacity of less than 0.9 meq/g ("MIT basis"), i.e., that segment of the claimed range from 0.1 to 0.9 meq/g. The

[35] In re Koller, 613 F.2d 819, 204 USPQ 702 (CCPA 1980).

[36] See In re Smith, 481 F.2d 910; 178 USPQ 620 (CCPA 1973),and Chisum, Patents §7.04.

[37] Smith, supra, 481 F.2d at 914; 178 USPQ at 624.

[38] See p. 13, supra.

[39] See, e.g., TR at 759-760.

[40] TR at 2561.

[41] The ALJ's finding that the prior art DEAE-Sephadex A-50 microcarrier has a charge capacity within the "alternative definition" has nothing to do with the description requirement. Rather, it relates to novelty. However, since the "alternative definition" is not the definition of the invention set forth in the claims, it is immaterial to the question of novelty of the claimed invention.

[42] ID at 12-18, 109-124.

ALJ recognized that cell culturing is an art, but pointed to testimony by one of respondents' witnesses as demonstrating that those skilled in the art could not employ lower charge capacity microcarriers to effect good cell growth without first determining "by complex, drawn out experimentation which, if any, of these lowest charge microcarriers would effect good cell growth, and then only after testing each such material with a variety of anchorage-dependent cells, nutrient media, pH conditions, etc."[43]

[6] The enablement requirement set out in the first paragraph of section 112 requires that the specification contain sufficient information to enable a person skilled in the relevant art to make and use the invention. We find that the claims are not invalid for failure of the specification to comply with the enablement requirement.[44]

[7] It may be true that those of ordinary skill in the art may have to experiment with various culturing parameters before being able to use a microcarrier having a charge capacity of less than 0.9 meq/g. The patents specifically contemplate such experimentation and do not distinguish what experimentation might be required on the basis of charge capacity. Experimentation is not inconsistent with enablement, providing that it is not undue.[45] Thus, the fact that experimentation may be complex, as testified to in this case, does not necessarily make it undue, if the art typically engages in such experimentation. This appears to be the case with cell culturing.[46] [47]

4. *Anticipation (35 U.S.C. §102)* [48]

The ALJ found that the claims of the '654 patent are anticipated by the prior art DEAE-Sephadex A-50 microcarrier, known to have a charge capacity of 3.5 ± 0.5 meq/g ("conventional basis"). The ALJ found that this indicates that a DEAE-Sephadex A-50 microcarrier existed with a charge capacity of 3.0 meq/g ("conventional basis") and found that when this charge capacity is converted using the agreed-upon conversion formula, a value of 5.01 meq/g ("MIT basis") is obtained, which he found to be within the "corrected" claimed range of 0.12 to 5.36 meq/g ("MIT basis").[49] The "corrected" range was computed by taking into account certain "error factors." These "error factors" are those referred to in the discussion of the description requirement.[50]

We find that the claims are not invalid for anticipation by DEAE-Sephadex A-50. Even if some DEAE-Sephadex A-50 beads were manufactured with a charge capacity of 3.0 meq/g ("conventional basis"), for the reasons discussed above, this charge capacity must be converted and then compared with the actual charge capacity expressed in the claims as they appear in the patent, not as "corrected" by the ALJ. Such a comparison shows that DEAE-Sephadex A-50 lies outside the claims and so does not anticipate the claimed invention.[51]

5. *Obviousness (35 U.S.C. §103)* [52]

[8] Even if a claimed invention is not identically disclosed in the prior art, section 103 provides that it is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

The ALJ, considering all the prior art references together, concluded that the claimed inventions would have been obvious to a person of ordinary skill in the art at the time they were made. We agree with the ALJ that the claims are invalid for obviousness under 35 U.S.C. §103, but it is necessary to amplify the reasoning leading to our conclusion.

[9] As the ALJ noted, the appropriate analysis to measure the extent to which respondents have carried their burden with respect to obviousness is that set out by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 466-467 (1966) wherein the Court stated:

> Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Therefore, we must examine the scope and content of the prior art and ascertain the differences between the prior art and the claims. While numerous prior art references are of record and were considered by the ALJ, our discussion is limited to the most pertinent references.

A. DEAE—Sephadex A-50; Pharmacia brochure [53]

The use of DEAE Sephadex A-50 as a microcarrier is of fundamental importance in assessing the question of obviousness. It is mentioned in numerous references, and warrants an introductory discussion. DEAE-Sephadex A-50 is an ion exchange resin which had been manufactured by respondents for many years prior to the filing date of the patents. It is sold by respondents in the form of small, porous beads for use in ion exchange chromatography. These beads comprise an inert cross-linked dextran matrix to which DEAE groups have been attached. The attached DEAE groups are dispersed throughout the matrix; each attached DEAE group bears a positive charge and is thus the charged group for this ion exchanger. The counter ion for DEAE-Sephadex A-50, as sold, is negatively-charged chloride ion. It is this ion which is exchangeable with other negatively-charged ions, i.e., anions. Thus, DEAE-Sephadex A-50 is an anion exchanger. The total capacity of DEAE-Sephadex A-50 is 3.5 ± 0.5 meq/g ("conventional basis"). At the time the parent application for the patents was filed, it was known that ions in the vicinity of the charged groups competed for these groups and that the greater the ionic strength, the greater the competition for these binding sites. This binding of the charged groups results in a reduced capacity.

The claimed invention is essentially identical to DEAE-Sephadex A-50, except for having a lower total charge capacity.

B. Van Wezel Nature article [54]

In October 1967, A.L. van Wezel reported the successful use of DEAE-Sephadex A-50 beads as microcarriers for growing mammalian cells, including anchorage-dependent diploid and primary cells. Van Wezel indicated that cell adherence and growth appeared to be due to the positive charge on DEAE-Sephadex A-50, noting that this was not surprising in view of the fact that mammalian tissue cells are negatively charged. Van Wezel did not state any lower limit for positive charge beyond which cells would not attach and grow. Van Wezel reported that the maximum growth rate of the cells in his microcarrier cultures was about the same as in (conventional) monolayer cultures, but that higher cell concentrations could be achieved by changing the medium. Van Wezel closed his report by stating: "The optimal conditions for culturing cells and viruses by this culture method have still to be found."

C. Van Wezel et al. Biotechnology and Bioengineering article [55]

In 1969, van Wezel and his coworkers again reported the use of DEAE-Sephadex A-50 beads as a microcarrier for growing anchorage-dependent mammalian cells. Among other things, they noted that when the quantity of DEAE-Sephadex A-50 exceeded 2 mg/ml, a "toxicity phenomenon" was encountered "unless the beads are pretreated

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[43] ID at 119.

[44] We note that complainants are correct that the question of enablement does not arise with respect to claims 4, 10, and 19 of the '534 patent and claims dependent therefrom since these claims cover only microcarriers above 0.9 meg/g, about which there is no dispute as to enablement.

[45] In re Angstadt and Griffin, 537 F.2d 498; 190 USPQ 214 (CCPA 1976).

[46] We note that there is no dispute as to the operability of CYTODEX 2, which is admittedly within the claims of the patent and has a charge capacity of less than 0.9 meg/g. Respondents argue that the operability of CYTODEX 2 does not necessarily show enablement. This may be true, but it is respondents' burden to show nonenablement. This they have failed to do.

[47] The ALJ found that "the disclosure of the suit patents is inadequate to enable those skilled in the art to make or use microcarriers having charge groups concentrated only on their surfaces." ID at 117. However, this finding is not relevant to our analysis since the claims do not contain such a limitation.

[48] ID at 18-25, 124-147.

[49] The ALJ did not find the '534 patent claims anticipated. Respondents' argument with respect to the '534 patent is such that it depends on anticipation of the '654 patent claims. See also note 23, supra.

[50] See p. 16, supra.

[51] In a footnote in their posthearing brief, respondents perform a computation purporting to "correct" the converted charge capacity of DEAE-Sephadex A-50 and then compare it with the claims as set out in the patents. RPB (Answers to Commission Questions) at 8. This argument is inconsistent with the conversion formula agreed upon by the parties, which purports to be complete. It also comes late and depends on the (doubtful) existence of the so-called "error factors."

[52] ID at 25-38, 147-169.

[53] This discussion of DEAE-Sephadex A-50 is based on the numerous discussions of it in the prior art references, including the Pharmacia brochure entitled: Sephadex Ion Exchangers, A Guide to Ion Exchange Chromatography (RX-12).

[54] A.L. van Wezel, "Growth of Cell-Strains and Primary Cells on Microcarriers in Homogeneous Culture," Nature 216:64 (1967); CX-5.

[55] Van Wezel et al., "Homogeneous Cultivation of Animal Cells for the Production of Virus and Virus Products," Biotechnology and Bioengineering, 11:875 (1969); RX-17.

with serum." Noting the expense of serum pretreatment, they mentioned that "[r]ecent experiments to obviate this expensive treatment by coating the beads with collodion show promise."

D. Van Wezel treatise article [56]

In 1973 van Wezel reported again on microcarrier cell culture in a treatise article. In that article van Wezel stated:

> From all materials tested DEAE-Sephadex A-50 appears to be most suitable to serve as microcarrier. The negatively charge tissue cells adhere very easily to the positively charged DEAE-Sephadex A-50, and the density of DEAE-Sephadex beads, after swelling, is about the same as the density of the culture medium. A disadvantage is that a slight inhibition of cell growth is found at concentrations exceeding 1 mg DEAE-Sephadex A-50 per milliliter culture medium. This can be obviated by coating the beads with a nitrocellulose product.

The coating procedure which is said to overcome the "slight inhibition of cell growth" at higher microcarrier concentrations is described in detail in the article.[57]

E. Horng and McLimans article [58]

In 1975, Horng and McLimans published an article on microcarrier culture of calf anterior pituitary cells. The abstract of that article states in pertinent part:

> Calf anterior pituitary cells were * * * successfully cultivated in a microcarrier suspension culture system. DEAE-Sephadex was demonstrated to be a satisfactory type of microcarrier. The cells readily attached to the bead and, after a short lag period, they actively proliferated on the bead surface to yield growth of a predominately epithelial cell type. Under specific conditions the microcarrier supported primary cell growth up to levels of 2×10^6 cells per ml. High bead concentrations inhibited cell growth. The inhibition could be overcome by using proportionately higher cell inoculum so that a concentrated culture with 5×10^6 cells per ml. was achieved. The inhibitory effect of high bead concentration was found to be due to the absorption of serum protein and certain growth enhancing factors.

F. Horng dissertation [59]

In March 1975, shortly after the Horng and McLimans article was accepted for publication, Horng, in his doctoral dissertation, described, among other things, the use of DEAE-Sephadex A-50 as a microcarrier for growing calf anterior pituitary cells. It states, in pertinent part (pages 157–159), as follows:

> 5.2.4 Absorption character and the growth inhibition
>
> Van Wezel and his coworkers reported cellular growth inhibition at high bead concentrations. The mechanism of such inhibition has not been reported. Instead, nitrocellulose was later employed for coating the beads without, however, showing the effectiveness of the coating. It should be noted that the concentrations of the beads employed after coating was lower than that routinely employed in this study. Under these conditions we found no significant inhibitory action.
>
> The inhibitory action appeared to be caused by the absorption of serum protein as well as a growth enhancing activity present in post trypsinization fluid.
>
> Experimental evidences can be summarized as follows:
>
> 1. In petri dish cultures subjected to statistical analysis, the inhibitory reaction was found to be caused by the absorption of medium components rather than the release of toxic substances. A serum supplement added to the absorbed medium substantially reduced the inhibitory reaction.
> 2. In petri dish cultures used beads proved to be superior to fresh bead preparations. On the other hand, used medium proved inferior to fresh medium for culture growth. Since the possibility of the release of toxic substance was excluded, it was evident that the beads removed some components from the medium.
> 3. Absorption of serum protein was quantitated. This was correlated with the inhibitory reaction.
> 4. In spinner cultures, the serum supplement reduced the inhibitory reaction without, however, totally eliminating the reaction. This suggested that absorption of components other than serum protein from the culture fluid may be involved.
> 5. By treating high bead concentrations with spent medium, cell growth can be enhanced. The presence of a growth enhancing activity in spent medium occurred within the first week of the culture.
> 6. The release of the growth enhancing activity did not take place during the culture period. After cell dissociation the post trypsinization fluid can be separated from the dissociated cells. This fluid showed the presence of the growth enhancing activity. Neither the cell homogenate from an equivalent amount of minced tissue, nor the amount of serum employed for trypsin inactivation, displayed the same activity.
> 7. By treating the post trypsinization fluid with beads the activity can be depleted.
> 8. The inhibitory reaction at high bead concentration can be eliminated by a combined treatment of beads with the post trypsinization fluid and serum.
>
> Thus, it is believed that the inhibitory reaction at high bead concentration has essentially been overcome.

G. United States Patent No. 4,036,693 (Levine patent)

This patent, entitled "Treatment of Cell Culture Microcarriers," was issued to David W. Levine, William G. Thilly, and Daniel I. C. Wang on July 19, 1977, based on an application filed February 2, 1976.[60] It discloses and claims, among other things, a method of treating positively charged microcarriers, such as those produced by reacting polydextran beads with DEAE, by contacting them with macromolecular polyanions, such as carboxymethylcellulose, prior to and/or during use in cultures. Such treatment is said to overcome "deleterious effects previously observed in attempts to use these microcarriers in cell culture systems".[61] Specifically, the prior art microcarriers referred to are DEAE-Sephadex A-50, and the "deleterious effects" are those "which prevent good cell growth," as indicated in "van Wezel's published data."[62] The patent also states:

> While not wishing to be bound by the following theory, it is believed that the macromolecular polyanion is effective in improving cell growth because it competes with medium and cell produced nutrients for absorptive sites on the microcarrier surfaces where cells do not attach.[63]

It is important to note that no specific macromolecular ion is required. The rationale given in the Levine patent for large (macro) molecular weight is "to provide sufficient charges upon the polyanion so that it will remain bound to bead surfaces once it becomes attached." [64] Other than that, the only requirement is that the anion be "nontoxic to growing mammalian cells." [65] Some specific macromolecular polyanions which are said to be suitable include "negatively charged polysaccharides and proteins," particularly carboxymethylcellulose.[66]

H. The Canadian patent [67]

The Canadian patent, owned by respondent Pharmacia AB, describes an anion exchanger particularly useful for the chromatographic separation of large molecules. Example 1 describes such an anion exchanger comprising cross-linked dextran to which positive-charge-carrying dimethylaminoethyl (DMAE) groups are attached. It has an ion exchange capacity of 1.9 meq/g ("conventional basis"), which is 2.4 meq/g ("MIT basis"), and thus is within the claims of the patents here.[68] Example 4 of the patent describes a cross-linked dextran bead with DEAE groups attached and having a charge capacity of 2.75 meq/g on the "conventional basis." The Canadian patent generally discloses how to make anion exchangers with

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[56] Van Wezel, "Microcarrier Cultures of Animal Cells," Tissue Culture, Methods and Applications, P. F. Kruse and M.K. Patterson, eds., Academic Press, New York, pp. 372 ff. (1973).

[57] The article also notes that satisfactory results were obtained with DEAE-Sephadex A 25 and QAE-Sephadex ion exchange beads, which have charge capacities of 3.5 ± 0.5 and 3.0 ± 0.4 meg/g ("conventional basis"). Plastic beads, such as specially treated polystyrene and nylon II, were found to be unsatisfactory because cells did not adhere firmly enough to them. Van Wezel also reported the apparently successful use of Spherosil beads (a special kind of porous glass bead) as a microcarrier by the Institut Pasteur, but noted that these beads may be "too heavy to be kept in suspension at low stirring speeds, while at high speeds the cells may not easily attach to the beads."

[58] Chi-Byi Horng and William McLimans, "Primary Suspension Culture of Calf Anterior Pituitary Cells on a Microcarrier Surface," Biotechnology and Bioengineering, Vol. XVII, pages 713-722 (1975) (accepted for publication December 20, 1974); CX-47.

[59] Chi-Byi Horng, Culture of Mammalian Cells on Microcarrier Surface, Dissertation Submitted to the Faculty of the Graduate School of the State University of New York at Buffalo (March 1975); RX-7.

[60] CX-6.

[61] Abstract, 11. 8-10.

[62] Col. 2, l. 35 — col. 3, l. 3.

[63] Col. 4, 11. 6-11.

[64] Col. 4, 11. 45-50.

[65] Col. 4, 11. 57-59.

[66] Col. 4, l. 63 — col. 5, l. 5.

[67] No. 651, 507, issued October 30, 1962.

[68] See, e.g., TR at 400.

charge capacities from 0.1 to 6.0 meq/g, as set out in its claim 3.

The anion exchangers of the Canadian patent are identical in all essential respects to the claimed invention, except that there is no evidence that anyone attempted to grow cells on them prior to the filing date of the patents here.

I. Whatman DE 52 beads [69]

This material, commercially available since 1973, is an ion-exchange material composed of positive-charge-carrying DEAE groups attached to beads comprising a cellulose matrix. It has a charge capacity of 1.0 meq/g ("conventional basis"). It is not disputed that when this value is converted to the "MIT basis," it falls within the claimed range. The Whatman ion exchanger beads are identical in all essential respects to the claimed invention, except that there is no evidence that anyone attempted to grow cells on them prior to the filing date of the patents here.

J. Servacel DEAE-32 beads;[70] *Inooka article*

This material, available since at least 1970, is an ion exchange material composed of cellulose beads to which positive-charge-carrying DEAE groups are attached. It has a charge capacity of 1.0 meq/g ("conventional basis"), which, when converted, falls within the narrowest of the claimed ranges. The Servacel ion exchange beads are identical in all essential respects to the claimed invention, except that there is no evidence that anyone attempted to grow cells on them prior to the filing date of the patents here. However, in 1969, Dr. Shoshi Inooka reported attachment of MH129F (mammalian) cells to "DEAE-cellulose (Serva)." [71]

K. The Levine Birmingham Paper [72]

In September 1975, Dr. Levine, Dr. I. C. Wang, and Dr. Thilly presented a paper entitled "Optimizing Parameters for Growth of Anchorage-Dependent Mammalian Cells in Microcarrier Culture" at the First International Cell Culture Congress at Birmingham, Alabama. Like Horng's, their experiments eliminated the presence of a soluble toxic factor released by the beads and concluded that the "toxic effect" observed by van Wezel was due to "significant uptake of nutrients by the beads." [73] They stated further that:

> Our solution to the problem of nutrient leaching is to add to the medium a negatively charged non-nutritive component to compete with the positively charged exchange sites on the beads. Use of carboxymethycellulose (CMC), a polyanion, has given excellent results. [74]

This is, of course, no more than what the Levine patent discloses. The authors then state:

> A second approach to the problem of nullifying nutrient absorption is also being pursued. In this case, we are attempting to synthesize a carrier which is optimal for cell adhesion and growth. A survey of possible carrier material is shown in Table II. The survey experiments consisted of bringing together cells, medium and test materials in plates. Two criteria for successful spinner operation were applied: adhesion of cells to the carrier surface and cell spreading with accompanying overgrowth. Our results confirmed the desirability of a positively charged surface. [75]

As noted above, similar evaluations had been done by Horng and van Wezel with the same result. In the Birmingham paper, the authors go on to state:

> Therefore, we are in the process of establishing minimum workable charge densities for cell adhesion and growth and are attempting to place charged groups on both impervious bead supports (such as polyethylene and polystyrene) and on uncharged Sephadex G-50. In the case of our studies with modified Sephadex G-50, the key concepts of our efforts are to either concentrate all charges at the surface, leaving the center of the bead uncharged, *or simply to reduce the total milliequivalents per gram of carrier,* and thus reduce the total nutrient uptake. [76] [Emphasis supplied.]

There is a dispute as to whether the Birmingham paper is prior art. The conference at which the paper was orally presented was attended by 50-500 cell culturists. Prior to the conference, a copy of the paper was given to the head of the conference. Afterward, copies were distributed on request. These copies were distributed, without any restrictions, [77] to as many as six persons more than one year before the filing date of the involved patents.

We believe that the distribution of copies of the Birmingham paper without restriction makes that paper a "printed publication," within the meaning of 35 U.S.C. §102(b). In Garrett Corp. v. United States, 422 F.2d 874, 164 USPQ 521 (Ct. Cl. 1970), as in this case, there was no question that the reference was "printed," only whether it was a "publication." The court there found that "while distribution to government agencies and personnel alone may not constitute publication, distribution to [6] commercial companies without restriction on use clearly does." [78]

[10] Our determination is consistent with In re Wyer, 655 F.2d 221, 210 USPQ 790 (CCPA 1981), which views "printed publication" as a unitary concept, concerned with "probability of dissemination" and founded on the public policy of 35 U.S.C. §102(b) to prevent withdrawal of subject matter already in the public's possession. Under In re Wyer, a document may be deemed a "printed publication" upon a satisfactory showing that it has been disseminated or otherwise made available to the extent that persons interested and of ordinary skill in the subject matter or art, exercising reasonable diligence, can locate it. Here between 50 and 500 persons interested and of ordinary skill in the subject matter or art were actually told of the existence of the paper and informed of its contents by the oral presentation. The document itself was actually disseminated, without restriction, to at least 6 persons, on their request, indicating not only unrestricted actual dissemination but also indicating that any person in the art who knew of the paper (and at least 50 to 500 did) could have a copy for the asking.

In any event, it appears that complainants have admitted that the Birmingham paper is prior art. During the prosecution of the '534 patent, the Birmingham paper was cited by MIT in a Supplemental Citation of Prior Art. At the time this Supplemental Citation of Prior Art was filed, MIT apparently felt that the paper could only be available as prior art as a "printed publication," but appears to have argued in the Supplemental Citation of Prior Art that it was not in fact a "printed publication." The Examiner disagreed. In his next Office Action, he rejected all the then pending claims under 35 U.S.C §103 over the Birmingham paper. [79] The Examiner did not state the basis for using the Birmingham paper as a prior art reference, nor did he respond to MIT's "printed publication" argument. We do not know whether the Examiner felt the Birmingham paper was available on another ground or whether he simply rejected MIT's "printed publication" argument. In its next response, MIT argued only the merits of the Birmingham paper and did not contend that it was not available as prior art. [80] A Notice of Allowance then issued.

During the subsequent prosecution of the '654 patent, some claims were allowed in the Examiner's first action and others were rejected under 35 U.S.C. §112. No art rejections were made, but in the accompanying Notice of References Cited, the Examiner cited the Birmingham paper, thus indicating that it was available as a prior art reference. [81] In its response, MIT did not take issue with this, and a Notice of Allowance was duly issued.

Thus, aside from the question of whether the Birmingham paper is a "printed publication," complainants have acquiesced in its treatment as prior art, effectively admitting it to be so. [82]

The ALJ found that the subject matter of the claimed invention involved two arts, ion exchange chemistry or organic synthesis and cell biology. He also found the level of skill to be high, requiring at least an undergraduate degree in chemistry and/or biology and two or three years of actual experience. [83] These findings are not disputed here.

Viewing the foregoing, and the record as a whole, we conclude that the claimed inventions would have been obvious. The prior art DEAE-Sephadex A-50 ion exchange beads were well known to be useful as cell culture microcarriers. The only difference between DEAE-Sephadex A-50 beads and the claimed microcarriers is the lower charge capacity of the latter. The "toxicity" phenomenon noted by van Wezel with respect to high concentrations of DEAE-Sephadex A-50 beads was known to have been overcome by pretreatment with serum or a polyanion, such as nitrocellulose or carboxymethylcellulose. The Birmingham paper expressly states that to reduce the total charge capacity of DEAE-Sephadex A-50 would have the same effect as

[69] Described in, among other places, three Whatman brochures: RX-270, RX-271, RX-272.

[70] These beads are described in, among other places, two brochures: RX-273, RX-274.

[71] Inooka, "The Adsorption of Suspended MH129F Cells to DEAE Sephadex Particles," 20 Tohoku Journal of Agricultural Research, No. 1 (March 1969); RX-8.

[72] Levine et al., "Optimizing Parameters for Growth of Anchorage-Dependent Mammalian Cells in Microcarrier Culture," First International Cell Culture Congress, September 21-25, 1975, Birmingham, Alabama; CX-8.

[73] Birmingham paper, CX-8, p. 15.

[74] Birmingham paper, CX-8, p. 16.

[75] Birmingham paper, CX-8, p. 18.

[76] Birmingham paper, CX-8, p. 18.

[77] CTR at 43.

[78] Garrett, 422 F.2d at 878; 164 USPQ at 424.

[79] '534 Patent File History; CX-12, p. 363.

[80] '534 Patent File History, CX-12, p. 372.

[81] '654 Patent File History, CX-12, p. 49.

[82] In re Nomiya, 509 F.2d 566; 184 USPQ 607 (CCPA 1975).

[83] ID at 154.

these pretreatments.[84] [85] The Canadian patent and the Whatman and Servacel products clearly show how to achieve this reduced charge capacity, and indeed indicate that anion exchange beads with such a reduced charge capacity were already commercially available. The claimed inventions would thus have been obvious.

Patent Infringement [86]

Complainants have alleged infringement by three of respondents' products: CYTODEX 1, CYTODEX 2, and CYTODEX 3. The ALJ found that all three of the products infringed the claims of the patents. Respondents did not petition for review of the ALJ's finding that CYTODEX 1 and CYTODEX 2 infringe, but did petition for review of his finding that CYTODEX 3 infringes. Our review focuses on CYTODEX 3.

The ALJ found that [deleted] , not collagen, is the charge-carrying moiety on CYTODEX 3 whose molecular weight must be included in the conversion formula. He then found that when the molecular weight of only the [deleted] is used in the conversion formula, infringment is made out.

We find that complainants have not established that CYTODEX 3 infringes the claims. The function of any conversion formula is to account for the weight of all the moieties added to the dextran bead so that charge capacity in terms of the weight of the dextran bead alone can be ascertained. It is clear that collagen is attached to the dextran bead through the [deleted].[87] Therefore, the collagen and [deleted] must both be accounted for. The exclusion of collagen would mean that the conversion formula could not possibly account for the weight of the collagen.[88]

Industry in the United States [89]

[11] In order for the Commission to find a violation of section 337, there must exist an "industry, efficiently and economically operated, in the United States." [90] Relying on Certain Apparatus for the Continuous Production of Cooper Rod, Inv. No. 337-TA-52, USITC Pub. No. 1017 (1979) (Copper Rod), the ALJ found that the two patents at issue in the subject investigation are "integrally related" and consequently concluded that the industry should be defined as a single industry encompassing operations under both patents. After analyzing the nature and the significance of complainant's operations in the United States, the ALJ concluded that these operations were sufficient to warrant a finding that they constitute an "industry * * * in the United States."

Even though we have disposed of the patent validity issue negatively, we continue to reach each of the elements of violation which are on review in this investigation. The Commission determined to review the question of industry because of its important policy implications.[91]

[84] The Birmingham paper is not necessary to demonstrate obviousness. The Levine patent expressly states that its polyanions bind to positively-charged groups on DEAE-Sephadex A-50 microcarriers. This binding of charged groups reduces the number of positively-charged groups available for binding cells. The same reduction may be achieved by reducing the number of charge groups, i.e., reducing the total charge capacity. See, e.g., Sephadex Ion Exchangers, A Guide to Ion Exchange Chromatography, RX-12.

Further, it is only necessary to have known of the association of fewer charge groups with overcoming the "toxicity" problem, no matter what the cause of that problem. Thus, it is not necessary to know whether the "toxicity" phenomenon is associated with competition for the position-charge-carrying sites by (negatively-charged) components of the nutrient media, thus depleting the medium of nutrients and making these nutrients unavailable for cell growth. There is considerable evidence that, at least at the time the claimed invention was made, this association was thought to exist, but complainants deny that there is now an acceptable theory sufficiently explaining the "toxicity" phenomenon, referring to testimony by Dr. Thilly in this case that he is unaware of such a theory. We note that Dr. Thilly and the other inventors offered this very theory in the Levine patent and the Birmingham paper.

[85] Complainants have argued that the Birmingham paper does not suggest any particular charge capacity range. See, e.g., CTR at 12. However, this is of little significance, since complainants' claimed range encompasses virtually the entire possible range below that of prior art DEAE-Sephadex A-50.

[86] ID at 44-49, 202-215.

[87] See, e.g., the representation at CHB-54, which complainants agree is "probably basically accurate and certainly the best representation that exists." CTR at 40.

[88] Respondents argue that even if CYTODEX 3 literally comes within the language of the claims of the patents, it does not infringe because the reverse doctrine of equivalents applies. This doctrine, set forth in Westinghouse v. Boyden, 170 U.S. 537 (1898), holds that even if a product comes within the language of a claim, it does not infringe if its mode of operation is totally different from that of the patented invention. We do not reach this issue.

[89] ID at 54-72, 224-252.

[90] The question of the efficient and economic operation of a domestic industry has not been reviewed.

[91] See Rule 210, 54(a)(ii), 19 CFR §210.54(a)(ii).

[12] We determine that there are two industries, one encompassing complainants' operations under the '654 patent, and the other encompassing complainants' operations under the '534 patent.[92] However, we also determine that the nature and significance of complainants' operations in the United States under the '654 patent do not justify treatment as an "industry . . . in the United States," but that complainants' operations under the '534 patent in the United States do justify treatment as an "industry * * * in the United States."

The '654 patent covers microcarriers; the '534 patent covers a method for obtaining cell by-products. Complainants use the '534 method to produce interferon. Combining the operations under these two patents is not justified because exploitation of the patents results in two clearly separate articles of commerce, i.e., microcarriers and interferon. In contrast to the present investigation, the Commission, in Copper Rod, found a single industry where apparatus and method patents and several trade secrets were involved. This finding was based on the fact that these property rights, as actually exploited, did not result in segregable products, but rather a single, integral system "sold as a 'package' comprising apparatus components, licensing of patent and trade secret know-how, engineering and start-up operations, and other technical assistance, etc." [93] Further evidence that the exploitation of the patents in the present investigation results in two distinct articles of commerce is provided by the products' identifiable, individual performances in the marketplace. The fact that the '654 microcarriers are used in the '534 process by complainants simply means that complainants' operations under the '534 patent constitute an internal, captive market for complainants' imported SUPERBEAD microcarriers covered by the '654 patent. In other words, combining operations under these two patents would be to confuse the market served by an industry with the industry itself.

1. Operations under the '534 patent

Complainant Flow has contracted to supply human fibroblast interferon to the National Cancer Institute. This operation, known as the Beta Interferon Program, is conducted in the United States and employs the method of the '534 patent.[94] Thus, there is an "industry * * * in the United States" under the '534 patent.

2. Operations under the '654 patent

As to the industry encompassing complainants' operations covered by the '654 patent (the patented microcarrier industry), the nature and significance of complainants' activities in the United States do not justify treatment as an industry "in the United States."

As the ALJ noted, complainants' SUPERBEAD microcarriers are manufactured entirely in Scotland.[95] Indeed, they are marked "Made in the U.K." Furthermore, complainants' SUPERBEAD microcarriers are packaged entirely in Scotland. In this investigation, the package insert which is printed in the United States is of little consequence. The ALJ divided the quality control tests for the SUPERBEAD microcarriers into four categories: (1) packaging check; (2) sterility; (3) physical chemistry; and (4) functionality. Initially, all quality control tests were performed in the United States. However, as Flow Labs Scotland's personnel became more adept at the techniques, certain quality control tests were performed on site in Scotland. Consequently, quality control tests have been performed in Scotland since at least 1981, and the tests that are performed in the United States are essentially redundant.

In his analysis, the ALJ focused particularly on the functionality test, noting that it was the single most important quality control test. From 1977 through June 1981, the functionality test was only performed by Flow in the United States. However, we note that in June 1981, Flow Labs began to perform the full functionality test in Scotland. It was not until 1982 [deleted] functionality test was performed a second time in the United States on some shipments of SUPERBEAD microcarriers.[96] Furthermore, the 17 percent value alleged to be added by this redundant test reflects intracompany pricing. The inclusion of the value of this test is also questionable since it appears to reflect the cost of the additional functionality testing for those SUPERBEADs used in the Beta Interferon Program [deleted].

[92] We note that the fact that the '654 patent is a division of the '534 patent means the two patents are directed to independent and distinct inventions as provided by 35 U.S.C. §121, under which divisions may be required.

[93] Copper rod, supra, at 55.

[94] ID at 62.

[95] ID at 229.

[96]

[97] [98]This additional functionality testing would not be relevant to the domestic industry defined by the '654 patent.

The ALJ found that by royalty payments and other means Flow supports research at MIT "in microcarrier technology." Flow conducts research and development which include "the Beta Interferon Program, [deleted] production devoted to improving Superbead production protocols, and cell systems research devoted to studying and improving microcarriers, culture media, and other cell culturing factors."[99] The ALJ found that between 1980 and 1982 Flow Labs U.S. spent [deleted] on "Superbead development" and that for 1983, [deleted] had been allocated to [deleted] research and development, [deleted] million to the Beta Interferon Program, and [deleted] to cell research and development.[100] It is apparent to us that the vast bulk of the research and development relied upon relates only to the Beta Interferon Program, i.e., operations under the '534 patent. Thus, we find that they cannot be considered as operations under the '654 patent. Furthermore, the extent to which the remaining research deals with operations under the '654 patent is not clear.[101]

The ALJ noted that Flow has a marketing network of regional sales representatives, but noted that they are responsible for "a full line of tissue culture products, so only a small percentage of their time is spent promoting or processing sale of Superbeads." [102] We find the activities here to be more than would be undertaken by any importer, and in any event they are of a minimal nature.[103]

Finally, the ALJ pointed to the technical product support provided to customers, analogizing it to the service activities in Certain Airtight Cast Iron Stoves, Inv. No. 337-TA-69, USITC Pub. No. 1126 (January 1981).[104] We determine that complainants' "technical service" amounts only to product support and is not of the same nature as the repair and installation activities found in Stoves; in any event, the significance of such activities is minimal.

Based on the record, we determine that the nature and extent of complainants' operations in the United States under the '654 patent are insufficient to constitute an "industry * * * in the United States."

Injury

Even though we have disposed of the questions of unfair practices and industry, we continue to reach this last element of violation which is on review in this investigation. The injury issue in this case is whether the alleged unfair practices in the importation and sale of respondents' products have the effect or tendency to substantially injure the industry defined above.[105] It is complainants' burden to establish such substantial injury and that such injury is caused by respondents' unfair practices.

[13] To prevail under section 337, complainants must prove not only that respondents committed the unfair practices alleged, but also that respondents' unfair practices have the effect or tendency to substantially injure a domestic industry. Commission practice has emphasized the separate nature of the injury and unfair practice requirements; each element requires independent proof. The establishment of patent infringement does not release complainants from the burden of establishing substantial injury, or of showing the requisite causal connection between the imports and the injury.[106]

[97] At least [deleted] of the total cost of complainants' SUPERBEAD microcarriers is the cost of the dextran beads. CTR at 15. These dextran beads are manufactured abroad by respondents as their Sephadex G-50 product. CTR at 35. Whether purchases originate in the United States or not is not relevant to an assessment of the significance of complainants' operations in the United States.

[98] The ALJ noted that of the [deleted] kg of SUPERBEADs produced from 1977 to 1982, [deleted] kg have been shipped to the United States, of which [deleted] kg have been used in Flow's Beta Interferon Program. ID at 233.

[99] ID at 234.

[100] ID at 241.

[101] The ALJ found that comparing the [deleted] in sales of SUPERBEADs between 1978 and 1982 to the research and development expenditures "on Superbeads alone" between 1980 and 1982, complainants' "domestic activities related to quality assurance and development add relatively more to the product than is added abroad." ID at 245. However, this comparison overlooks [deleted].

[102] ID at 234.

[103] See also Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles, Inv. No. 337-TA-122, USITC Pub. No. 1300 (October 1982), aff'd, Schaper Manufacturing Co. v. U.S. International Trade Commission, F.2d, 219 USPQ 665 (CAFC 1983).

[104] ID at 239.

[105] The question of whether respondents' alleged unfair practices have prevented the establishment of an industry in the United States was decided adversely to complainants by the ALJ in his ID and is not on review.

[106] Chairman Eckes and Commissioners Stern and Lodwick reference the Recommended Determination of the ALJ in Certain CT Scanner and Gamma Camera Medical Diagnostic Imaging Apparatus, Inv. No. 337-TA-123 (March 4, 1983) at 180.

1. Operations under the '534 patent

These operations are the only operations which constitute an "industry * * * in the United States." However, the product of this industry is beta interferon, which respondents do not import. Therefore, there can be no injury to this industry within the meaning of section 337.[107]

2. Operations under the '654 patent

The ALJ found that there were two markets for microcarriers: "the traditional research market, consisting of laboratories and university research departments conducting experiments in cell culturing and requiring only small quantities of microcarriers, and the macro, or industrial market, consisting of vaccine and veterinary product manufacturers which engage in large-scale propagation of cells and cell by-products." [108] He also found that "the greatest potential for large-volume sales of microcarriers is the industrial market"; indeed, he found that "[T]he future viability of the microcarrier technique appears to depend on its acceptance and widespread use by the industrial market." [109] However, he found that "no potential large-scale user has adopted the microcarrier technique." [110]

Nevertheless, the ALJ found that "the failure of the industrial segment of the market to expand according to the parties' original expectations should not be allowed to obscure the presence of the laboratory market," and then proceeded to conduct his injury analysis with respect to the laboratory market.[111] He found the industry to have been injured in this market, and concluded that such injury was "substantial." He also found a tendency to substantially injure.

We find that complainants are not suffering substantial injury as a result of respondents' alleged unfair practices. We also find that there is no tendency to substantially injure the domestic industry that we have assumed to exist for purposes of this analysis. In assessing injury, it is important to note that only a [deleted] proportion of Flow's SUPERBEAD microcarriers are sold to third parties; the [deleted] are consumed by Flow itself to produce beta interferon under its contract for NCI. Flow's production capacity for SUPERBREAD microcarriers in 1982 was [deleted] kg.[112] [deleted] kg of SUPERBEADs was produced in Scotland from 1977 to 1982.[113] Of this, [deleted] kg have been shipped to the United States, of which [deleted] kg was for use in the Beta Interferon Program. The remaining [deleted] kg appears to be completely accounted for by sales to third parties in the United States.

The industrial segment of the market, the only segment which might have been expected to make large-scale purchases, has, as the ALJ found, simply failed to adopt microcarrier technology. The remaining segment of the market, the "laboratory segment," [deleted]. However, even conducting an injury analysis on the basis of this laboratory market, complainants have failed to show any substantial injury or tendency to substantially injure caused by the subject practices.

The "laboratory segment" comprises researchers in commercial uses, nonprofit institutions, and Government laboratories.[114] Any decline in sales to researchers in commercial establishments is properly attributable to nonacceptance of microcarriers for industrial use. As to Government laboratories, there can be no injury as a matter of law because the Government has a royalty-free license under both patents for any Government purpose, including the right to second source from anyone, including Pharmacia.[115] This extends to Government-funded research in non-Government laboratories, which include some of the nonprofit institutions. A large proportion of such research was said to be Government funded.[116] [117]

Thus, only a small portion of the laboratory market can possibly be injured as a result

[107] Assuming that complainants' activities under both patents were combined to find an industry, our conclusion that there is no injury would be the same since the only operation "in the United States" under the '654 patent which could be included in such a combination is - [deleted].

This operation, to the extent it exists in the United States, is so minimal that the effective result of combining it with complainants' operations under the '534 patent would be to define the industry in terms of operations covered by the '534 patent alone. See p. 37, supra.

[108] ID at 254.

[109] ID AT 255.

[110] ID at 255.

[111] ID at 257-258.

[112] ID at 78.

[113] Production of the SUPERBEAD microcarriers in Scotland [deleted]. ID at 78.

[114] CTR at 63-65.

[115] CTR at 176, 179-183, 184.

[116] CTR at 185.

[117] Furthermore, we cannot overlook complainants' statement at the Commission hearing that there was no intent by MIT or Flow to enforce the patents against personnel in research laboratories, whether those research laboratories are nonprofit, other educational institutions, or commercial concerns. CTR at 176-177.

of respondent's activities. And even in this small portion, complainants have not met their burden. This is shown by evidence that in addition to the failure of the industrial market to accept microcarrier technology, [deleted] CYTODEX 1, which was introduced in 1978, the same year as complainants' SUPERBEAD, experienced [deleted] CYTODEX 2 was introduced in 1981; the year CYTODEX 1 and SUPERBEADS [deleted] kg was sold in 1981, [deleted] for CYTODEX 1 and SUPERBEADs (approximately [deleted] kg), although close to the [deleted] for SUPERBEADs alone. One the other hand, CYTODEX 2 sales [deleted] and the combined sales of CYTODEX 1 and CYTODEX 2 [deleted].

The ALJ found that between 1978 and 1982 respondents imported and sold [deleted] kg of CYTODEX products, while Flow sold [deleted] kg and used an additional [deleted] kg of SUPERBEADs in its Beta Interferon Program. He concluded from this that "Pharmacia's market penetration is greater than [deleted] percent, and their volume of imports, far from being de minimis, is substantial." [118]

While the ALJ noted that it was difficult to evaluate complainants' evidence of lost sales, he found some evidence that: (1) many of Flow's customers have purchased microcarriers from both Flow and Pharmacia, (2) many appear to have switched to Pharmacia, and (3) some customers have stopped buying microcarriers altogether.[119] However, complainants' National Sales Manager was unable to confirm conclusively at trial Flow's allegedly lost sales to Pharmacia, but merely referred to purchases of respondents' products by customers of complainants.[120] These may not necessarily be lost sales. The ALJ found that "Complainants' loss of customers appears to be the result of many factors, including a recessionary economy, initial difficulties with quality control, and customer difficulties with the technique," but concluded that "as a result of Pharmacia's market penetration, Flow has demonstrated loss of customers to Pharmacia." [121]

There is no clear evidence of lost customers. There is substantial evidence that the subject imports were not brought as substitutes for complainants' products,[122] because the record shows that many customers purchased from both complainants and respondents. Researchers tend to seek multiple sources of supply. Furthermore, any lost sales which might have occurred may be noninjurious sales under the Government's rights. Clearly some customers were lost for reasons having nothing to do with respondents. While market penetration may mean respondents have customers, market penetration alone does not mean that respondents obtained those customers at the expense of complainants.[123] We find that under the facts of this investigation, the market penetration of respondents' microcarriers does not indicate substantial injury or tendency to injure.

The ALJ found that [deleted] [124] [deleted].

While respondents' CYTODEX products are sold at a lower price than SUPERBEADs, underselling alone does not establish lost sales. In fact, there is an indication that lost sales are not occurring, i.e., customers are buying both products. Furthermore, because of the nature of the laboratory market, price does not appear to be an important factor.

The ALJ found that Flow had excess capacity to produce microcarriers, but stated that the main source of this excess capacity has been "the failure of microcarrier technology to achieve its anticipated acceptance in the industrial market." [125] Nevertheless, the ALJ found that respondents' "significant market penetration, volume of sales and lower priced product is a contributing factor to Flow's excess capacity." We find that complainants' excess capacity is due to lack of acceptance of microcarriers in the potentially large industrial market, not the small laboratory market. The contributing factors discussed by the ALJ relate to the small laboratory market and, thus, any contribution they may have made is correspondingly small. [appendix omitted.]

[118] ID at 262-263.
[119] ID at 260.
[120] ID at 260.
[121] ID at 262.
[122] Four other, noninfringing, microcarriers are available, two of which are sold at less than half the price of respondents' products.
[123] ID at 262.
[124] ID at 264.
[125] ID at 268.

Patent and Trademark Office
Trademark Trial and Appeal Board

In re Mars, Incorporated

Decided Nov. 30, 1983

TRADEMARKS

1. Drawings (§67.30)

Presentation of mark for registration in typewritten form means that mark may be displayed in any style of lettering.

2. Class of goods — In applications to register (§67.205)

TTAB must consider all channels of trade that are peculiar to goods when limitations are not set forth in registration or application for registration before it.

3. Class of goods — Particular cases — Similar (§67.2073)

Use of identical mark for candy bars, and for fresh citrus fruits, is likely to cause confusion.

4. Identity and similarity — How determined — Doubt against newcomer (§67.4067)

Doubt in Lanham Act Section 2(d) cases should be resolved against newcomer.

Appeal from Trademark Examining Attorney.

Application for registration of trademark of Mars, Incorporated, Serial No. 202,876. From decision refusing registration, applicant appeals. Affirmed.

John J. Byrne, Washington, D.C., for applicant.

Before Allen, Fruge, and Sams, Members.

Allen, Member.

Before us is an appeal from the Trademark Examining Attorney's refusal of registration of the term CANYON for "candy bars" under Section 2(d) of the Trademark Act, 15 U.S.C. §1052(d) (1976). In particular, the refusal of registration is based on the likelihood of confusion of the mark subject of the application for registration with the mark reproduced below, subject of an existing registration for "fresh citrus fruits–namely, oranges, lemons and grapefruit": [1]

Canyon

Both appellant and the Examining Attorney have filed briefs. Appellant waived oral argument. We affirm.

[1] Since the mark sought to be registered is presented in typewritten form, the fact that the mark of the cited registration is in script is irrelevant to the issue before us. Presentation of a mark for registration in typewritten form means that the mark may be displayed in any style of lettering, including, presumptively, the same style as that used by the owner of the cited registration. Pfizer, Inc. v. Cody John Cosmetics, Inc., 211 USPQ 64, 68 (TTAB 1981). Accordingly, the only issue which we have to decide is whether the goods of the cited registration are sufficiently related in purchasers' minds as to be likely to result in confusion as to their source when sold under the identical mark CANYON.

There is no question that candy bars and fresh citrus fruit are distinguishable products. Fruits are grown; candy bars are man made from ingredients. Furthermore, while appellant has conceded these goods are "oftentimes sold in the same class of stores to the same class of customers" [2] (e.g. retail grocery markets and householders), they would not ordinarily be found in proximate locations in these channels. See, e.g. In re August Storck KG, 218 USPQ 823, 825 (TTAB 1983).

On the other hand, in other channels of distribution, these goods may be sold by the same distributor in a single package. For example, in holiday food packages sold by catalogue mail order houses and by department stores and specialty shops fresh fruits are frequently combined with cheese, nuts, cakes, cookies and candy and other such items. In mail order channels which are growing in popularity in our contemporary society, it is also not unlikely that a producer of fruit exploiting the holiday food package market would also produce candy of which fruit was a principal ingredient (e.g. chocolate covered fruit bars).

Moreover, as the Examining Attorney has pointed out in his brief, the goods are complementary in that they may be served or eaten together as a dessert or an after dinner treat. Doubtless this is one of the reasons they are

[1] Reg. 254,768, issued April 2, 1929; republished under Section 12(c), affidavit Section 8 accepted, Section 15 received; twice renewed to Mesa Citrus Growers, Mesa, Arizona.

[2] Copy of paper apparently filed on or about May 30, 1980, submitted by counsel for appellant July 31, 1981 to replace the Office file which had been lost.

the plaintiff must at least be able to allege facts that indicate that the defendant has enforced, or has sought to enforce, or has threatened to enforce, its fraudulently obtained patents against the plaintiff itself

* * * *

Indium v. Semi-Alloys at 1352-53, 219 USPQ at 800.

Before considering the allegations in the Amended Complaint, the Court is constrained to acknowledge, after consideration of the argument of counsel and further review of the relevant cases and authorities, that it would be a mistake to interpret "enforcement" too narrowly, and thereby limit the remedy of a Walker Process type antitrust action to competitors that have actually been sued or threatened with suit by the defendant. The concept must be broad enough to afford a remedy not only to those who actually produced an infringing article and were forced to stop by infringement suit or the threat thereof, but also to those who were ready, willing, and able to produce the article and would have done so but for the exercise of exclusionary power by the defendant. See SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1206, 209 USPQ 889, 901 (2d Cir. 1981) ("Where * * * the acquisition [of the patent] itself is unlawful, the subsequent exercise of the ordinarily lawful exclusionary power inherent in the patent would be a continuing wrong, a continuing exclusion of potential competitors.") (Emphasis added); See also, P. Areeda, D. Turner, Antitrust Law ¶335c at 174 ("[I]t is as unlawful to prevent a person from engaging in a business as it is to drive him from it * * * *"). Thus, "enforcement" in the context of claim that the plaintiff was injured by the enforcement of a fraudulently procured patent, does not require proof that the defendant expressly threatened plaintiff with an infringement suit. See Zenith Radio Corp. v. Hazeltine Research, Inc., supra, 395 U.S. 100, 161 USPQ 577. (Despite absence in record of any specific instance of infringement suit against manufacturer's existing or potential distributors or dealers, evidence of the defendant's more general acts of patent enforcement enabled trial court to infer "that the necessary causal relationship between the pool's conduct and the claimed damages existed." Id. at 125, 161 USPQ at 587).

In this instance, plaintiff alleges, inter alia, that it was a direct competitor among a relatively small field of suppliers to the relevant market; that the defendant fraudulently procured the patents in question, and then commenced a course of vigorously enforcing such patents; that between 1975 and 1982 the defendant had threatened with infringement suit or had actually sued every other supplier of tack-welded frame lids, driving all from the market except its co-conspirator; that since 1976, plaintiff was ready, willing, and able to produce tack-welded frame lids but was restrained by the defendant's vigorous course of enforcement; that after learning of grounds upon which the defendant's patents might be held invalid, plaintiff actually commenced producing tack-welded frame lids, whereupon defendant immediately contacted it regarding licensing, and filed suit against it in state court. The Court has already held, supra, that such allegations supply the grounds for a "reasonable apprehension" of an impending infringement suit, and therefore create a case or controversy within the Court's declaratory judgment jurisdiction. The Court now holds that such allegations are also sufficient to state that the plaintiff is a person "injured in his property by reason of anything forbidden in the antitrust laws * * * *" Clayton Act §4; 15 U.S.C. §15.

Without belaboring the point, it is also clear that the Amended Complaint also supplies allegations that correct the other deficiencies identified in the original Complaint, e.g. the relevant market, the scope of defendant's monopoly power.

Accordingly, defendant's motion to dismiss the Complaint pursuant to Rule 12(b)(1), (6) is hereby denied.[1] In view of the length and complexity of the Amended Complaint (and also in view of the season) defendant is afforded 30 days from the date of entry to answer.

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[1] On July 19, the Clerk's Office received from the defendant a motion for leave to file a Supplemental Amended Complaint and a request for expedited procedure. The Supplemental Amended Complaint would add allegations that, in May of this year, Semi-Alloys, through its Japanese agent, expressly threatened legal action under Semi-Alloy's corresponding patent against a Japanese would/be purchaser of Indium's tack-welded frame-lids.

Plaintiff's motion, which did not recite a return date, will be placed on the calendar for the Court's next regularly scheduled motion day, September 11, 1984, unless mutual consent of the parties. It is assumed that any need for an "expedited procedure" is obviated by this Memorandum-Decision.

Court of Appeals, Federal Circuit

Atlas Powder Company v.
E.I. Du Pont De Nemours & Company

No. 84-504
Decided Dec. 27, 1984

PATENTS

1. Specification — Sufficiency of disclosure (§62.7)

Use of prophetic examples does not automatically make patent nonenabling, burden being on patent challenger to show by clear and convincing evidence that prophetic examples together with specification's other parts are nonenabling.

2. Infringement — Substitution of equivalents — Basic, improvement or paper patent (§39.753)

Where accused has appropriated material features of patent, infringement will be found even when those features have been supplemented and modified to such extent that accused may be entitled to patent for improvement.

3. Infringement — Substitution of equivalents — In general (§39.751)

Patentee that was unable effectively to use product that accused successfully developed, is not estopped from asserting infringement on equivalence theory, since focus in assessing equivalence is on whether accused's product performs substantially same as claimed product in function, way and result, and not on patentee's ability to devise product equivalent to patented product.

Particular patents — Explosives

3,447,978, Bluhm, Ammonium Nitrate Emulsion Blasting Agent and Method of Preparing Same, decision holding claims 1-5, 7, 12-14, and 16-17, valid and infringed, affirmed.

Appeal from District Court for the Northern District of Texas, Higgenbotham, J.; 221 USPQ 426.

Action by Atlas Powder Company, against E.I. Du Pont De Numours & Company, and Alamo Explosives Company, Inc., for patent infringement, in which defendant counterclaims for declaration of patent invalidity. From Judgment for plaintiff, defendants appeal. Affirmed.

Garland P. Andrews, Roy W. Hardin, David L. Hitchcock, and Richards, Harris & Medlock, all of Dallas, Tex., for plaintiff.

Stanley Neely, and Locke, Purnell, Boren, Laney & Neely, both of Dallas, Tex., and Lawrence F. Scinto, Nels T. Lippert, and Fitzpatrick, Cella, Harper & Scinto, all of New York, N.Y., for defendants.

Before Markey, Chief Judge, and Baldwin and Miller, Circuit Judges.

Baldwin, Circuit Judge.

This is an appeal by E. I. du Pont De Nemours & Co. and its customer Alamo Explosives Co., Inc. (collectively, "Du Pont"). The appeal is from a final judgment of the United States District Court for the Northern District of Texas holding product claims 1-5, 7, 12-14, and 16-17 of U.S. Patent No. 3,447,978 ('978 patent), issued to Harold Bluhm on June 3, 1969 and assigned to the Atlas Powder Co. ("Atlas"), not invalid under 35 U.S.C. §§ 102, 103, and 112, not fraudulently procured, and infringed. We affirm.

Background

The district court opinion, reported at 588 F.Supp. 1455, 221 USPQ 426 (1983), contains a detailed description of the facts, familiarity of which is presumed herein.

Briefly, the '978 patent relates to blasting agents, i.e., chemical mixtures that are relatively insensitive to normal modes of detonation but can be made to detonate with a high strength explosive primer. By the mid-1960's, blasting agents consisted of two major types: "ANFO" and "water-containing."

An "ANFO" blasting agent comprised a mixture of particulate ammonium nitrate, usually in the form of small round aggregates known as "prills," and fuel oil (e.g., diesel fuel). They were widely used in mining and construction because of their low cost, ease of handling, and ability to be mixed at the blast site rather than prepackaged at the plant. However, to work properly they could be used only in "dry" holes (without water) because water desensitized the mixutre, rendering it nondetonable.

A "water-containing" blasting agent, which was water resistant, generally comprised a slurry of particulate ammonium nitrate (or other oxidizing salt), a solid or liquid fuel, at least 5 percent water, and, as a sensitizer to increase explosive power, either a high explosive such as TNT or a chemical

such as nitric acid. Often, a gelling agent was added, particularly in the chemical sensitized slurries, to prevent the separation of sensitizers from slurry by forming a gel (a colloid in which the disperse phase has combined with the continuous phase to produce a viscous, jelly-like product). The use of sensitizers in water-containing blasting agents made preparation and handling more difficult and dangerous and, hence, more costly.

Before the '978 invention, Atlas manufactured a gelled slurry blasting agent called Aquanite, based on U.S. Patent No. 3,164,503, issued to Gehrig and assigned to Atlas. Aquanite used as a sensitizer nitric acid, which was highly caustic to skin and clothing and tended to separate out of the product even in the presence of a gelling agent, thereby reducing the product's stability and shelf life. Also, Aquanite was "hypergolic," i.e., it ignited wood, coal and various chemicals upon contact, which was suspected of causing the blasting agent to detonate prematurely.

The Invention

In 1965, Atlas assigned Harold Bluhm to investigate stabilizing its Aquanite gel. Bluhm experimented with various "emulsions" that did not contain nitric acid or a gelling agent. (An emulsion is a stable mixture of two immiscible liquids; a "water-in-oil" emulsion has a continuous oil and discontinuous aqueous phase; an "oil-in-water" emulsion is the reverse.) In early 1966, Bluhm formulated an intimately mixed water-in-oil, water resistant emulsion blasting agent. The product was sensitized with entrapped air rather than high explosives or chemicals and is the subject matter of the claims at issue. Representative is Claim 1:

1. An emulsion blasting agent consisting essentially of:

an aqueous solution of ammonium nitrate forming a discontinuous emulsion phase;

a carbonaceous fuel forming a continuous emulsion phase;

an occluded gas dispersed within said emulsion and comprising at least 4% by volume, thereof at 70°F. and atmospheric pressure; and

a water-in-oil type emulsifying agent;

said carbonaceous fuel having a consistency such that said occluded gas is held in said emulsion at a temperature of 70°F.

Claim 1 is the only independent claim in suit. The other, dependent claims describe various ingredients, such as miscrospheres for the occluded gas, additional fuels (e.g., aluminum), specific ranges of ingredients, and various properties of the blasting agent.

Du Pont's Activities

Du Pont sold a gelled slurry blasting agent until the latter part of the 1970's. In 1976, Du Pont formed a team to study the feasibility of an emulsion blasting agent. The team succeeded in making a water-in-oil emulsion blasting agent which Du Pont began making and selling in August 1978. Atlas sued for infringement in December 1979.

The District Court Proceedings

A non-jury trial was held between January 28 and February 2, 1982. Du Pont asserted invalidity of the '978 patent under sections 102(a), 103, and 112, "fraud" on the Patent and Trademark Office (PTO), and noninfringement. The district court rejected those assertions for the product claims at issue, holding that: (1) the claimed invention was not anticipated by the prior art; (2) the claimed invention would not have been obvious in view of the prior art; (3) the claims were not invalid for the patent's failure to comply with the "best mode," enablement, and "overclaiming" requirements of 35 U.S.C. §112; (4) the patent was not procured by "fraud" on the PTO; and (5) Du Pont's products infringed the claims under the doctrine of equivalence. On appeal, Du Pont contests those holdings, except for the one on best mode.

The district court denied Atlas increased damages and attorney fees because Du Pont had not willfully infringed the '978 patent claims and the case was not "exceptional." The district court also held that product claims 6, 13, and 15 were not infringed and that process claims 18–30 were invalid. Atlas has not appealed those holdings.

Issues

(1) Whether the district court was clearly erroneous in finding the invention of the patent claims at issue not anticipated by the prior art.

(2) Whether the district court erred in holding that the invention of the patent claims at issue would not have been obvious.

(3) Whether the district court erred in holding the patent claims at issue not invalid because of nonenablement.

(4) Whether the district court erred in holding no "fraud" on the PTO; i.e., no inequitable conduct.

(5) Whether the district court was clearly erroneous in finding that Du Pont's products infringed the '978 claims under the doctrine of equivalents.

Opinion

I. Standard of Review

The burden is on Du Pont, as appellant, to establish that the district court's ultimate fact findings (e.g., anticipation, infringement) were clearly erroneous, that the district court's legal conclusions (e.g., §103 obviousness, §112 enablement) were erroneous, or that the findings underlying the ultimate findings or conclusions were clearly erroneous. The "clearly erroneous" standard is satisfied if we are left with the firm conviction that error has been committed. See, e.g., Raytheon Co. v. Roper Corp., 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983), cert. denied, 53 U.S.L.W. 3255 (U.S. Oct. 2, 1984).

II. Presumption of Validity

Under 35 U.S.C. §282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984), cert. denied, 53 U.S.L.W. 3225 (U.S. Oct. 2, 1984). In that regard, the district court committed an error.

After correctly stating that the presumption of validity must be overcome with clear and convincing evidence, the district court stated that, if pertinent prior art were not cited to the PTO, as was the case here, the presumption is weakened and Du Pont must prove invalidity by only a preponderance of the evidence. That is incorrect. Though the introduction of prior art not before the PTO may facilitate meeting the challenger's ability to meet the burden of proof on invalidity, the presumption remains intact, the burden of persuasion remains on the challenger, and the "clear and convincing" standard does not change. See, e.g., Jervis B. Webb Co. v. Southern Systems, Inc., 742 F.2d 1388, 1392 & n.4, 222 USPQ 943, 945 & n.4 (Fed. Cir. 1984); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534, 218 USPQ 871, 875 (Fed. Cir. 1983).

The error, however, was harmless. Indeed, it helped Du Pont at trial by lowering the standard of proof needed to prove its case. Even with the lower standard, Du Pont was unable to succeed.

III. Anticipation

The district court's determination of no anticipation was a factual one that should be reversed only if appellant shows that it was clearly erroneous. See, e.g., Lindemann Machinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). Du Pont attempts to satisfy its burden by arguing that U.S. Patent No. 3,161,551, to Egly, et al., anticipated the claimed invention. We conclude, however, that the district court's finding of no anticipation was not clearly erroneous.

Egly, which Du Pont referred to at oral argument as the "closest prior art," describes an emulsion of ammonium nitrate, water, fuel oil, and water-in-oil emulsifying agent. Though Egly teaches the presence of solid ammonium nitrate prills as an essential ingredient, Du Pont argues that the '978 claims, because of the phrase "consisting essentially of," does not exclude the presence of those prills. See, e.g., In re Herz, 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). Du Pont is correct. However, the district court found that Egly "does not mention air or gas as an ingredient in their explosives" and occluded air is an element of the claims. Hence, there is no anticipation under §102, because the exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771-72, 218 USPQ 781, 789 (Fed. Cir. 1983).

Du Pont asserts that Bluhm conceded in answer to an interrogatory that the first reduction to practice of the claimed invention was on January 14, 1966, and that Mr. Bluhm's notebook shows the composition prepared on that date to be identical to Egly's i.e., an emulsion without occluded air. Because the first reduction to practice was identical to Egly's product, Du Pont argues, the claimed invention is anticipated by Egly. Atlas argues that the notebook entry reveals that occluded air was present in the composition prepared on January 14, 1966, and hence, the first reduction to practice was not identical to Egly's composition. Atlas appears to be correct but, in any event, the district court's anticipation analysis properly focused on the claimed invention, which includes occluded air, not on Atlas' characterization of the January 14, 1966 experiment as the first reduction to practice.

IV. Obviousness

Though an invention is not anticipated by 35 U.S.C. §102, a patent should not issue if the differences between the claimed invention and prior art are such that the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. 35 U.S.C. §103. In assessing nonobviousness a court should answer certain factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) so-called "secondary" considerations, e.g., long felt need, unexpected results, commercial success. See, e.g., Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d at 1538, 218 USPQ at 876; Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 1575, 222 UPSQ 743, 746 (Fed. Cir. 1984). The "secondary" considerations, when present, may assist the court in determining nonobviousness without falling prey to hindsight reasoning.

Here, the district court made findings on the content of the prior art, the level of ordinary skill in the art, the differences between the prior art and the claimed invention as a whole, and then concluded that the claimed invention was nonobvious. Du Pont has not shown error in the legal conclusion of nonobviousness, or clear error in the underlying findings.

Content of the Prior Art and Differences Between It and the Claimed Invention

In addition to Egly, discussed above, the district court considered several patents and articles.

Atlas' Gehrig patent describes a blasting agent containing particulate ammonium nitrate, a solution of nitric acid in water, and fuel oil. Though the mixture may be an emulsion, the primary thrust of Gehrig is using a gel. Gehrig notes that, when an emulsion is used, the product quickly separates into its various components. Gehrig recommends that the emulsion be used within 24 hours to avoid separation. The gel form is considered desirable to stabilize the product for storage.

The claimed invention differs from Gehrig because Gehrig requires nitric acid as an essential ingredient. The '978 claims exclude the presence of nitric acid because the essence of the claimed composition is the elimination of nitric acid and the claim phrase "consisting essentially of" excludes ingredients that would "materially affect the basic and novel characteristics" of the claimed composition. In re Herz, 537 F.2d at 551, 190 USPQ at 463; In re Janakirama-Rao, 317 F.2d at 954, 137 USPQ at 895.

Gehrig does not teach substituting nitric acid with air to sensitize the product. Though it suggests the use of microballoons containing air as a stabilizer, it also discusses heating the product to remove entrapped air.

U.S. Patent No. 3,052,578, to Davis, describes a blasting agent comprising a blend of fuel oil and ammonium nitrate poured over solid ammonium nitrate. An oil-in-water, not water-in-oil, emulsifying agent is suggested to disperse the fuel. Though an emulsifying agent is used for dispersing purposes, the reference does not discuss forming an emulsion, and it does not suggest use of occluded air.

Two papers by Coxon relate to water resistant blasting agents. The first describes a water-in-oil emulsion of fuel oil and ammonium nitrate poured over solid ammonium nitrate. The second is similar, but prefers an oil-in-water emulsifying agent. Neither paper teaches the presence of occluded air; instead, the blasting agent requires solid ammonium nitrate. Thus, both Coxon papers, as well as Davis, are similar to Egly.

U.S. Patent No. 3,004,842, to Rowlinson, describes melting solid ammonium nitrate and mixing it with fuel oil and an emulsifying agent to form a solid blasting agent. A small amount of water may be added to reduce the melting point of the ammonium nitrate. Foaming agents can be added to increase the product's sensitivity.

U.S. Patent No. 3,453,158, to Clay, describes a gel or thickened slurry containing aqueous ammonium nitrate, a gelling agent or thickener, air bubbles serving as a sensitizer, and particulate fuels or sensitizers. The district court found that Clay does not use an emulsion, let alone a water-in-oil emulsion, and that finding has not been shown to be clearly erroneous.

Level of Skill in the Art

The district court found that the person of ordinary skill in the art would be one skilled in the art of explosives formulation, having knowledge of and experience with the chemical and physical properties of explosives. The person should be a chemist or chemical engineer with at least a bachelor's degree and several years of practical experience. Also, he or she should have a working knowledge of the principles of emulsion chemistry as applied to explosives formulation.

"Secondary" Considerations

The district court stated that, in light of "substantial differences" between the prior art and the product claims, it is not necessary to consider secondary factors, though they were raised by Atlas. Hence, the district court's opinion does not contain a section on "secondary criteria" or otherwise attempt to identify such criteria under the label. Nevertheless, the district court found that "[t]he Bluhm patent solved the problem of finding a water resistent ANFO blasting agent that did not require chemical sensitizers." Moreover, the district court in essence found that the solution to the problem was unexpected.

Though the prior art describes water-in-oil emulsions containing dissolved ammonium nitrate, fuel oil, and a water-in-oil emulsifying agent, the district court found that the art does not suggest that the emulsion itself can serve as a blasting agent. Egly, for example, teaches that such an emulsion — without occluded air — serves as a sensitizer that can be poured over solid ammonium nitrate to form a blasting agent. Gehrig teaches that the emulsion serves as a blasting agent only in the presence of nitric acid. That the Egly sensitizer itself serves as a blasting agent when occluded air is added, or that the Gehrig blasting agent could serve in that capacity without nitric acid, was unexpected. Though occluded air was recognized as an ingredient that could be included in blasting agent compositions, e.g., to stabilize the nitric acid containing product of Gehrig, the district court found that the references simply did not teach "that aeration can substitute for chemical sensitizers [e.g., nitric acid] in slurry explosives or that a water-in-oil emulsion is the most efficient system for entraining air."

Moreover, the district court found (and it has not been shown to be clearly erroneous) that the references cited by Du Pont deemphasize occluded air in emulsions and, hence, teach away from the importance of aeration. Egly and Davis do not mention air or gas as an ingredient in their explosives, and one of the Coxon papers teaches that detonation performance may be improved by using emulsifiers to eliminate frothing (air) from explosives.

Conclusion on Nonobviousness

In light of the differences between the claimed invention and prior art, the '978 solution to a troublesome problem, and the unexpected result that a water-in-oil emulsion of ammonium nitrate, fuel oil, and a water-in-oil emulsifying agent can serve as a blasting agent in the presence of occluded air, we agree with the district court's conclusion of nonobviousness.

Du Pont argues that it would have been obvious in 1966 to leave the nitric acid sensitizer out of Gehrig's slurry, intimately mix the fuel oil and ammonium nitrate, and sensitize the product in some other way, e.g., with air. We agree with the district court, however, that neither Gehrig nor the other prior art suggests those changes to obtain an emulsion blasting agent. As stated by the district court:

> It is quite a leap from recognition that dry ANFOs could be sensitized by aeration to realization that if an ANFO slurry was placed in the proper form of a water-in-oil emulsion and aerated, it would not require chemical sensitizers for detonability. This leap would not have been obvious in 1966.

V. Enablement

The district court rejected Du Pont's arguments of "overly broad," "overclaiming," and "non-enablement," and its argument that the broad scope of the claims is not supported by the limited disclosure present. In essence, those arguments are one: the '978 disclosure does not enable one of ordinary skill in the art to make and use the claimed invention, and hence, the claimed invention is invalid under 35 U.S.C. §112, ¶1.

To be enabling under §112, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. Raytheon Co. v. Roper Corp., 724 F.2d at 960, 220 USPQ at 599. That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive. See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed. Cir. 1983), cert. denied, 53 U.S.L.W. 3226 (U.S. Oct. 2, 1984); In re Angstadt, 537 F.2d 498, 503, 190 USPQ 214, 218 (CCPA 1976). Determining enablement is a question of law. Raytheon Co. v. Roper Corp., 724 F.2d at 959-60, 220 USPQ at 599.

Du Pont argues that the patent disclosure lists numerous salts, fuels, and emulsifiers that could form thousands of emulsions but there is no commensurate teaching as to which combination would work. The disclosure, according to Du Pont, is nothing more than " a list of candidate ingredients" from which one skilled in the art would have to select and experiment unduly to find an operable emulsion.

The district court held it would have been impossible for Bluhm to list all operable emulsions and exclude the inoperable ones.

Further, it found such list unnecessary, because one skilled in the art would know how to select a salt and fuel and then apply "Bancroft's Rule" to determine the proper emulsifier. Bancroft's Rule was found by the district court to be a "basic principle of emulsion chemistry," and Du Pont has not shown that finding to be clearly erroneous.

We agree with the district court's conclusion on enablement. Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude * * * possible inoperative substances * * * *" In re Dinh-Nguyen, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1973). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971). That, however, has not been shown to be the case here.

Du Pont contends that, because the '978 examples are "merely prophetic," they do not aid one skilled in the art in making the invention.[1] Because they are prophetic, argues Du Pont, there can be no guarantee that the examples would actually work.

[1] Use of prophetic examples, however, does not automatically make a patent nonenabling. The burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling. Du Pont did not meet that burden here. To the contrary, the district court found that the "prophetic" examples of the specification were based on actual experiments that were slightly modified in the patent to reflect what the inventor believed to be optimum, and hence, they would be helpful in enabling someone to make the invention.

Du Pont argues that of some 300 experiments performed by Atlas before the filing of the '978 patent application, Atlas' records indicated that 40 percent failed "for some reason or another." The district court agreed that Atlas' records showed 40 percent "failed," but found that Atlas' listing of an experiment as a "failure" or "unsatisfactory" was misleading. Experiments were designated "failures," the district court found, in essence because they were not optimal under all conditions, but such optimality is not required for a valid patent. Decca Ltd. v. United Staes, 544 F.2d 1070, 1077, 191 USPQ 439, 444-45 (Ct. Cl. 1976). Accord, E. I. du Pont de Nemours & Co. v. Berkley & Co., 620 F.2d 1247, 1260, 205 USPQ 5, 10 (8th Cir. 1980). Cf. Raytheon Co. v. Roper Co., 724 F.2d at 958, 220 USPQ at 598. The district court also found that one skilled in the art would know how to modify slightly many of those "failures to form a better emulsion. Du Pont has not persuaded us that the district court was clearly erroneous in those findings.

Du Pont asserts that Atlas was able to produce suitable emulsions with only two emulsifiers, "Atmos 300" and "Span 80," and therefore, the disclosure should be construed to read upon only those two emulsifiers. However, Du Pont did not prove that the other disclosed emulsifiers were inoperable. The district court credited testimony by Atlas' expert, Dr. Fowkes, to the effect that he had successfully formed a number of detonable emulsions using a variety of emulsifiers specified in the '978 patent. Further, the district court found that one skilled in the art would know which emulsifiers would work in a given system. Indeed, the district court found that Du Pont's own researchers had little difficulty in making satisfactory emulsions with the emulsifying agents, salts, and fuels listed in the '978 patent. Those findings have not been shown to be clearly erroneous.

In sum, we conclude that Du Pont has failed to show that the district court erred in determining enablement.

VI. Inequitable Conduct

This court has held "inequitable conduct" in the PTO to be a more appropriate label than "fraud." J. P. Stevens & Co. v. Lex Tex Ltd., Nos. 84-754,-761, slip op. at 9, 223 USPQ 1089, 1092 (Fed. Cir. Nov. 9, 1984). Hence, this opinion will use the phrase "inequitable conduct" rather than "fraud."

Inequitable conduct requires proof by clear and convincing evidence of a threshold degree of materiality of the nondisclosed or false information. That threshold can be established by any of four tests: (1) objective "but for"; (2) subjective "but for"; (3) "but it may have been"; and (4) 37 C.F.R. §1.56(a), i.e., whether there is a substantial likelihood that a reasonable examiner would have considered the omitted or false information important in deciding whether to allow the application to issue as a patent. Slip op. at 10, 223 USPQ 1094-95. The PTO standard is the appropriate starting point because it is the broadest and most closely aligns with how one ought to conduct business with the PTO. Id.

Inequitable conduct also requires proof of a threshold intent. That intent need not be proven with direct evidence. It may be proven by showing acts the natural consequences of which are presumably intended by the actor. Id. Proof of deliberate scheming is not needed; gross negligence is sufficient. Gross negligence is present when the actor knew or should have known of the materiality of a withheld reference. Id. at 11, 223 USPQ at 1096. On the other hand, simple negligence, oversight or an erroneous judgment made in good faith is insufficient. Id.

Once the thresholds of materiality and intent are established as facts, the court must balance them and determine as a matter of law whether the scales compel a conclusion that ineqitable conduct occurred. Id. If the court reaches that conclusion, it must hold the patent claims at issue unenforceable.

Du Pont argues that Atlas committed inequitable conduct by failing to tell the examiner that the examples were "prophetic" and, hence, in misleading the examiner into believing that the examples were actually performed. However, the district court found that the examples were written in the present tense to conform with the PTO requirements on prophetic examples. Moreover, the district court found that all but one of the examples were based on actual experiments and only slightly modified to reflect the inventor's notion of the most effective formulation. Consequently, the district court found, there was no intent on the part of Atlas to mislead the PTO. Du Pont has not shown those findings to be clearly erroneous. Even if intent could be inferred, and if the examples were prophetic but not disclosed to the examiner as such, Du Pont has not shown the nondisclosure to have been material, i.e., important to an exminer in allowing the patent to issue.

Du Pont asserts that Atlas' conduct cannot be distinguished from that in Grefco, Inc. v. Kewanee Industries, Inc., 499 F.Supp. 844, 208 USPQ 218 (D. Del. 1980), aff'd without publ. opinion, 671 F.2d 495 (3d Cir. 1981). We disagree. In Grefco, the patentee, to convince the examiner of the invention's superiority, presented "test results" based on tests that it knew never occurred, told the examiner the invention had been successfully tested when it had twice failed, and withheld information about those failures from the examiner. Intent and materiality were clearly established in Grefco, and the court in weighing the two factors held that there was inequitable conduct. That is not true here.

Du Pont argues that Atlas did not disclose its numerous "failures" and that it "padded" the disclosure with emulsifiers it knew would not work. The district court, however, found that Du Pont failed to prove that any of the emulsifiers were inoperative and the court found that the evidence on the "failed" experiments was not dispositive. Du Pont has not shown any clear error on the part of the district court in those findings.

Du Pont also alleges inequitable conduct in Atlas not disclosing to the examiner its Aquanite gel, the commercial version of the invention of its Gehrig patent. Though the district court found Aquanite to be "pertinent," it found no intent in the nondisclosure because Atlas had disclosed the Gehrig patent to the examiner. Du Pont has not shown any clear error in that finding. Cf. Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1568-69, 224 USPQ 195 (Fed. Cir. 1984). (Vandenberg disclosed a PX-15 device as prior art but failed to describe it as its own prior invention; the disclosure was held to be inconsistent with the intent necessary for inequitable conduct).

VII. Infringement

Literal Infringement

Determining infirngement requires claim construction as a preliminary step. See, e.g., Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). If properly construed claims read on the infringing product, there is literal infringement. Id. at 1571, 219 USPQ at 1142.

Du Pont's blasting agents are water-in-oil emulsions containing water, ammonium nitrate, fuel oil, occluded gas, and an emulsifying agent. Unlike the claimed invention, Du Pont uses as the emulsifying agent sodium oleate, which is formed in situ by adding sodium hydroxide and oleic acid to the other emulsion ingredients. Sodium oleate is normally an oil-in-water emulsifying agent but in the environment of the Du Pont product (i.e., a high salt concentration leading to

[1] The PTO Manual of Patent Examining Procedure (MPEP) §608.01(p)(D) (5th ed. 1983), states:

> Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. Paper examples should not be described using the past tense.

phase inversion), the sodium oleate acts as a water-in-oil emulsifying agent. The Du Pont product, and the in situ process of forming it, are the subject of U.S. Patent No. 4,287,100, issued to Owen and assigned to Du Pont.

The district court construed the '978 claim term "water-in-oil type emulsifying agent" as excluding compounds that normally function as oil-in-water emulsifying agents, e.g., sodium oleate. That claim construction prompted the district court to find no literal infringement. Atlas does not contest that finding and, for purposes of appeal, we accept it and the underlying claim construction.

Doctrine of Equivalents

A product that does not literally infringe can infringe under the doctrine of equivalents. Designed to protect a patentee from an infringer who appropriates the invention but avoids the literal language of the claims, the doctrine allows a finding of infringement when the accused product and claimed invention perform substantially the same function in substantially the same way to yield substantially the same result. Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 608-09, 85 USPQ 328, 330 (1950); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 900, 221 USPQ 669, 679 (Fed. Cir. 1984), cert. denied, 53 U.S.L.W. 3226 (U.S. Oct. 2, 1984). The district court found that the Du Pont products and the claimed invention are equivalent, and Du Pont has not shown that finding to be clearly erroneous.[2]

The district court's opinion clearly delineates the Graver Tank tripartite test of substantially the same function, way, and result but then, adopting an analysis found in Ziegler v. Phillips Petroleum Co., 483 F.2d 858, 870, 177 USPQ 481, 487 (5th Cir.), cert. denied, 414 U.S. 1079, 180 USPQ 1 (1973), focuses on the "function, purpose, and quality" of the emulsifying agents of Du Pont and the claimed invention. That focus, argues Du Pont, was wrong because it ignored the Graver Tank tripartite test. We disagree.

Though Graver Tank articulates the tripartite test of "function, way, and result," it also states that the doctrine of equivalence should not be the prisoner of a rigid formula. Moreover, Graver, which as here compared a claimed mixture with an accused mixture in which one ingredient of the claimed mixture was changed, stated:

> "Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform."

Id. at 611, 85 USPQ at 331.

Such consideration makes sense. Where, as here, the accused product avoids literal infringement by changing one ingredient of a claimed composition, it is appropriate for a court to consider in assessing equivalence whether the changed ingredient has the same purpose, quality, and function as the claimed ingredient. If it does, the accused and claimed products should meet the Graver Tank tripartite test of "function, way, and result."

That the district court focused on the function, quality, and purpose of the emulsifying agents does not mean it ignored the basic tripartite test which it expressly referred to in the opinion. We infer from that express reference, and from the opinion as a whole, that the district court did in fact find that the "function, way, and result" test was satisfied. See ACS Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1582, 221 USPQ 929, 936 (Fed. Cir. 1984) (this court will infer findings that were obviously necessary to the court's opinion).

Du Pont argues that, because its emulsion product was patented after the '978 patent issued, its product avoids infringement by equivalence. According to Du Pont, "*so long as direct infringement is lacking*, the grant of a patent to an accused infringer constitutes a prima facie determination of non-equivalence and, accordingly, of non-infringement" (Du Pont's emphasis). Atlas disagrees. So do we.

Du Pont concedes that, if Atlas patents A + B + C and Du Pont then patents the improvement A + B + C + D, Du Pont is liable to Atlas for any manufacture, use, or sale of A + B + C + D because the latter directly infringes claims to A + B + C. Du Pont urges, however, that it is not liable for manufacture, use, or sale of patented improvement A + B + C′, even though A + B + C′ is "equivalent" to A + B + C. We reject Du Pont's attempted distinction. Whether Du Pont makes A + B + C + D or A + B + C′, Du Pont has used the gist of Atlas' invention to devise a patentable composition. There is no compelling reason to hold Du Pont liable for infringement in one instance but not the other.[3]

[2] We agree with Bendix Corp. v. United States, 199 USPQ 203 (Ct. Cl. Trial Div. 1978), aff'd, 600 F.2d 1364, 204 USPQ 617 (Ct. Cl. 1979). There the trial judge said that where defendant has appropriated the material features of the patent in suit, infringement will be found "even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement." 199 USPQ at 221-22. Though Du Pont argues that cases from other courts support a contrary result, we are not bound by those cases and in any event find them unpersuasive.[4]

More persuasive is the reasoning of Herman v. Youngstown Car Mfg. Co., 191 F. 579, 584-85 (6th Cir. 1911). After finding equivalence, the court rejected appellant's contention that its receipt of a patent negates infringement:

> A patent is not the grant of a right to make or use or sell. It does not, directly or indirectly, imply any such right. It grants only the right to exclude others. The supposition that a right to make is created by the patent grant is obviously inconsistent with the established distinctions between generic and specific patents, and with the well-known fact that a very considerable portion of the patents granted are in a field covered by a former relatively generic or basic patent, are tributary to such earlier patent, and cannot be practiced unless by license thereunder.
>
> Another reason sometimes advanced for supposing that the structure of the second does not infringe the claim of the first patent is that the Patent Office has declared that a patentable difference exists. The premise is sound, but not the conclusion. In examining the second application, the Patent Office has no concern with the scope of the claim of the first, and does not and must not pay any attention thereto. It is concerned only with the early disclosure by the specification and drawings. Patentable difference does not of itself tend to negative infringement. It may just as well be based upon infringement, plus improvement; and improvement may lie in addition, simplification, or variance.

See also Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42, 3 USPQ 40, 44 (1929) (where there is substantiality of function, way, and result, infringement cannot be avoided by any presumptive validity attaching to the issuance of a patent to the infringer); Sure Plus Mfg. Co. v. Kobrin, 719 F.2d 1114, 1117 (11th Cir. 1983) (no presumption of non-infringement arises from the issuance of a patent to the infringer); Freeman v. Altvater, 66 F.2d 506, 512, 18 USPQ 186, 192-93 (8th Cir.), cert. denied, 290 U.S. 696 (1933) (the court after finding equivalence stated that the issuance of a patent merely raises a presumption of validity, not a presumption of non-infringement).

Du Pont contends that one skilled in the art in 1966 would not have known that the '978 and Du Pont products were equivalent. It is not a requirement of equivalence, however, that those skilled in the art know of the equivalence when the patent application is filed or the patent issues. That question is determined as of the time infringement takes place. In Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1365, 219 USPQ 473, 483 (Fed. Cir. 1983), this court held that devices changing the patented invention with advances developed subsequent to the patent could infringe under the doctrine of equivalents. See also American Hosp. Supply Corp. v. Travenol Labs., Inc., 745 F.2d 1, 9, 223 USPQ 577, 583 (Fed. Cir. 1984).

[3] Du Pont also argues that Atlas is "estopped" from asserting that the '978 claims cover the use of an oil-in-water emulsifier such as sodium oleate because Atlas was unable to use that type of emulsifier effectively. We reject Du Pont's argument on two grounds.

First, finding equivalence is not inconsistent with a patentee's unsuccessful attempt to make the accused product. The focus in assessing equivalence is on whether the accused product performs substantially the same as the claimed product in function, way and result — it is not on the patentee's ability to devise a product equivalent to the patented

[2] One of Du Pont's products includes aluminum, which is not present in representative claim 1. It is, however, present in dependent claim 14. Moreover, the addition of an ingredient by Du Pont does not necessarily avoid infringement of claim 1. See, e.g., Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d 840, 848, 221 USPQ 657, 663-64 (Fed. Cir. 1984), cert. denied, 53 U.S.L.W. 3225 (U.S. Oct. 2, 1984); Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482, 221 USPQ 649, 653 (Fed. Cir. 1984).

[3] Of course, if A + B + C′ were patented because of unexpected results, those unexpected results might prompt a finding of no equivalence. That finding, however, would exist because, under the Graver Tank tripartite test, the "results" achieved by the claimed and accused products would be substantially different. The district court in this case did not find any such unexpected results. Though it found that Du Pont's products were more stable than those of the '978 patent, that is not necessarily inconsistent with equivalence. Equivalence does not require that the claimed invention and accused product have identical results; the results can be substantially the same and the accused product can be an improvement. Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d at 901-02, 221 USPQ at 679-80; Decca Ltd. v. United States, 544 F.2d 1070, 1080-81, 191 USPQ 439, 448 (Ct. Cl. 1976).

[4] We are bound by opinions of our predecessor courts, the Court of Claims and CCPA. South Corp. v. United States, 690 F.2d 1368, 215 USPQ 657 (Fed. Cir. 1982).

product. Indeed, the patentee's incentive to devise an equivalent product is often less than a competitor's, which alone may account for the competitor's success and the patentee's failure in devising the equivalent product. See, e.g., Leesona Corp. v. Varta Batteries, Inc., 522 F.Supp. 1304, 1328, 213 USPQ 222, 241 (S.D.N.Y. 1981).

Second, the record submitted to this court makes no reference to any type of estoppel. That strongly suggests that estoppel was not raised before the district court. Bockoven v. Marsh, 727 F.2d 1558, 1566 (Fed. Cir. 1984). Because a party may generally not argue on appeal an issue not raised below, Weinar v. Rollform Inc., 744 F.2d 797, 804, 223 USPQ 369, 372 (Fed. Cir. 1984); Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1388, 219 USPQ 569, 575 (Fed. Cir. 1983), the estoppel argument is not properly before us.

Du Pont also argues that, because its product is formed in situ, it is different from the claimed product. It is the claimed product, however, not the process of forming it, that is involved. The district court found that the Du Pont emulsion, though it uses what is normally an oil-in-water emulsifier, "acts as a water-in-oil emulsifier," "caus[ing] a water-in-oil emulsion to form," and is otherwise substantially the same as the '978 emulsion. Those findings have not been shown to be clearly erroneous.

Du Pont further contends that the district court erred in considering the "heart of the invention" in its infringement analysis. We disagree. Although there is no legally recognized "essence" or "heart" of the invention in determining validity, W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 53 U.S.L.W. 3226 (U.S. Oct. 2, 1984), it can be applicable in a determination of infringement under the doctrine of equivalents. Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983). Moreover, the district court's "heart of the invention" analysis was supplemental to its finding that the Graver Tank tripartite test was satisfied.

Finally, Du Pont argues that the district court erred in not addressing in its opinion which of the individual claims are infringed. However, the district court specified the infringing claims in its judgment, and we review judgments, not statements in opinions. See, e.g., Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d at 1463, 221 USPQ at 489. Reviewing the judgment, we conclude that the district court did not commit clear error in finding infringement of the claims on appeal.

VIII. Conclusion

Having considered all of Du Pont's arguments, the district court's decision that the '978 patent claims on appeal (1-5, 7, 12-14, and 16-17) are not invalid under 35 U.S.C. §§102, 103, and 112, that there was no inequitable conduct before the PTO, and that the claims on appeal were infringed, is *affirmed*.

Court of Appeals, Federal Circuit

State Industries, Inc. v. A.O. Smith Corporation

No. 84-590

Decided Jan. 3, 1985

PATENTS

1. Accounting — Increased or trebled damages or profits (§11.35)

Keeping track of competitor's products and designing new, better, or cheaper functional equivalents should not be discouraged by punitive damage awards except in cases where conduct is so obnoxious as clearly to call for them.

2. Notice and marking patented (§46)

Patent must exist and one must have knowledge of it for patent to be willfully infringed, and "patent pending" notice does not give one such knowledge and is not even guarantee that application has been filed, nor is filing guarantee that any patent will issue.

Particular patents — Water Heaters

4,263,879, Lindahl, Water Heater, holding of validity and infringement affirmed.

Appeal from District Court for the Middle District of Tennessee, Wiseman, J., 221 USPQ 958.

Action by State Industries, Inc., against A.O. Smith Corporation, for patent infringement, in which defendant counterclaims for declaration of patent invalidity and noninfringement. From judgment for plaintiff, defendant appeals. Affirmed in part, and reversed in part.

Glen O. Starke, and Andrus, Sceales, Starke & Sawall, both of Milwaukee, Wis. (Gary A. Essmann, Milwaukee, Wis., on the brief) for appellant.

Paul R. Puerner, and Michael, Best & Friedrick, both of Milwaukee, Wis. (Glenn A. Buse, Milwaukee, Wis., on the brief) for appellee.

Before Rich, Baldwin, and Kashiwa, Circuit Judges.

Rich, Circuit Judge.

This appeal is from the October 5, 1983, Order of the United States District Court for the Middle District of Tennessee, Nashville Division, 221 USPQ 958 (1983). The court, sitting without a jury, held appellee's Lindahl patent No. 4,263,879 ('879), issued April 28, 1981, for "Water Heater," valid and willfully infringed. We affirm the holdings of validity and infringement, and reverse the holding that infringement was willful.

Background

State Industries, Inc. (State), which manufactures and sells industrial water heaters under its SANDBLASTER mark, sued its competitor A.O. Smith Corporation (Smith), which manufactures and sells a similar water heater under its LIME TAMER mark. The patent in suit is for a water heater designed to reduce sediment buildup, i.e., minerals such as lime, in the water heater tank. Sediment buildup reduces efficiency and eventually may cause tank failure.

The preferred embodiment of the invention is shown in Figs. 1 and 2 of the patent, reproduced below:

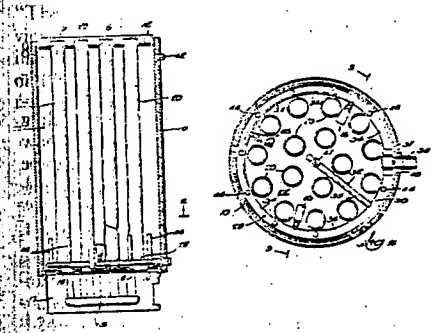

Fig. 1 is a sectional elevation of the water heater and Fig. 2 is a section on the line 2-2 of Fig. 1 showing the agitator assembly mounted in the bottom portion of the tank 22. Flue tubes 20 conduct hot gas from burner 15 through the water. The agitator assembly 28 includes a ring-shaped tubular member 30 positioned in the bottom of the tank closely adjacent to its side wall 10 and a secondary tubular member 32, connected to the ring-shaped member 30, which extends horizontally toward the center of the tank. Tubular member 30 has several small holes 34 and several venturi fittings 46 all directed toward the center of the tank at a level closely adjacent to the bottom of the tank. These openings are positioned so that the streams of water flowing from them are directed over and adjacent to the bottom of the tank.

The secondary tubular member 32 has several small holes 35 and, near its inner end an upwardly directed venturi fitting 47, which enhance the desired stirring action and help suspend the sediment in the center of the tank.

Thus, when hot water is withdrawn through outlet 42 at the top of the tank, cold water simultaneously flows into, and out of the openings in, the agitator assembly. The combined action of the water flowing from the openings in that assembly stirs up and suspends sediment which has settled to the bottom of the tank and ultimately carries it upward and out through the hot water outlet 42.

The '879 patent contains eight claims of which only claims 7 and 8 are relied on. Claim 7, directed to the water heater structure, is exemplary. It reads (paragraphing added):

> 7. A water heater comprising:
> a water tight tank means adapted to contain water under pressure;
> a source of heat for heating water inside said tank means;
> a hot water outlet means located in the top portion of said tank means for periodically withdrawing heated water from the top portion of said tank means;
> an agitator assembly means mounted in the bottom portion of said tank, said agitator assembly means including
> a tubular member connected to a source of water under pressure to be heated,
> said tubular member extending into said water tight tank means,
> said tubular member being imperforate other than having a plurality of small openings therein spaced along the length thereof to direct multiple streams of water under pressure into the tank each time water is drawn out of the top portion of said tank means through said hot water outlet means,
> said plurality of openings in said otherwise imperforate tubular member positioned so

one's own goods to the detriment of a competitor. *See L'Aiglon Apparel, Inc. v. Lana Lobell, Inc.*, 214 F.2d 649 [102 USPQ 94] (3rd Cir. 1954) (Section 43(a) created a new "statutory civil wrong of false representation of goods in commerce"); *Potucek v. Taylor*, 738 F.Supp. 466, 469 [16 USPQ2d 1383] (M.D. Fla. 1990) (Section 43(a) grew out of tort of false advertising). Congress amended § 43(a) enacting the Trademark Revision Act of 1988, which has been deemed to have expanded the Lanham Act to include commercial defamation claims. *National Artists Management Co. v. Weaving*, 769 F.Supp. 1224, 1229 [20 USPQ2d 1113] (S.D.N.Y. 1991); *Monoflo Int'l Inc. v. Sahm*, 726 F.Supp. 121, 126 n.10 [13 USPQ2d 1823] (E.D. Va. 1989).

[1] DPMI has moved to dismiss American Needle's § 43(a) claim on the grounds that the September 17th letter is not covered by the Lanham Act because it was not sent to the NBA for purposes of influencing consumers to purchase its licensed headwear. Section 43(a) of the Lanham Act provides in relevant part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> . . .
>
> (2) in commercial *advertising or promotion*, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a) (emphasis added). Nothing in the language of § 43(a), contrary to DPMI's position, specifically requires a false representation be intended to influence the ultimate consumer, whoever that might be. "[T]he allegation that the advertising language was false or misleading is sufficient to withstand a motion to dismiss, regardless of to whom the advertising was targeted." *Mylan Laboratories, Inc. v. Pharmaceutical Basics, Inc.*, 808 F.Supp. 446, 459 [25 USPQ2d 2002] (D. Md. 1992) (denying motion to dismiss § 43(a) claim where defendant circulated brochures to wholesalers, physicians, and pharmacists who were not the consumers of the defendant's products).

Although the Lanham Act does not require allegedly false statements to reach the consuming public before they are actionable, the Act requires that such statements be made in "commercial advertising or promotion." The term "commercial," as used in § 43(a)(2), refers to the business purpose for which the advertising or promotion is used. *National Artists Management*, 769 F.Supp. at 1232 (commercial advertising means advertising "for business purposes"); *see also* 134 Cong. Rec. S16973 (October 20, 1988) ("the word 'commercial' is intended only to eliminate any possibility that the section might be applied to political speech"). The September 17th letter discussed the termination of the Agreement and the alleged reasons therefore; accordingly, American Needle's § 43(a)(2) claim rests on whether the September 17th letter constitutes "advertising or promotion."

Neither "advertising" nor "promotion" are defined within the Lanham Act. As defined by Webster's, advertising is "the action of calling something to the attention of *the public* [especially] by paid announcements." Webster's Ninth New Collegiate Dictionary 59 (1986). The concept of public notification also occurs in the definitions of "advertise" and "advertisement." *Id.* Similarly, the definition of "promotion" utilizes the term "publicity." *Id.* at 942 ("the furtherance of the acceptance and sale of merchandise through advertising, publicity, or discounting"). Nothing in the Lanham Act suggests that "advertisement" and "promotion" should be given any interpretation other than their plain and ordinary meanings, which include the notion of public dissemination of information. *See Marcyan v. Nissen Corp.*, 578 F. Supp. 485, 507 [215 USPQ 629] (N.D. Ind. 1982) (plaintiff made no showing that complained of statement "was ever made available to the general purchasing public or in sufficient quantities to constitute an advertisement").

[2] The September 17th letter was an isolated individualized written statement about American Needle's alleged breach of the Agreement; that letter is at the opposite pole of clearly definable media advertising containing specific verifiable or disprovable statements and given wide distribution in commerce. The level of circulation required to constitute advertising and promotion will undeniably vary from industry to industry and from case to case. *See National Artists Management*, 769 F.Supp. at 1235 (speaking with twenty persons about their relationship with plaintiff in indisputably small and closely interconnected industry constituted commercial advertising and promotion). American Needle claims that, in the licensed head-gear industry, the September 17th letter achieves a negative effect on American Needle's commercial activities, and that this effect occurs as surely as if DPMI "had gone to a trade show and there said to retailers in attendance the same things about American Needle that it falsely said in the [September 17th] letter." While American Needle's statement may be correct, the difference is that public dissemination of false information to retailers at a trade show would most likely constitute "commercial advertising and promotion," while a single letter privately addressed to a non-consuming licensor does not.

Section 43(a)(2) contains the words "advertising" and "promotion," which include their attendant requirements of publicity. *See Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 [222 USPQ 292] (1985) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose"). To permit a single private correspondence to constitute either one of these terms for purposes of § 43(a)(2) liability would render their use superfluous and would sweep within the ambit of the Act any disparaging comment made in the context of a commercial transaction. The plain meaning of § 43(a)(2) does not permit this interpretation. Although the § 43(a)(2) is intended to reach commercial defamation claims, by its terms it requires more than an allegedly libelous, private letter delivered to a single entity.[2] Therefore, count IV of American Needle's complaint, brought under § 43(a)(2) of the Lanham Act, must be dismissed.

CONCLUSION

For the foregoing reasons, Count III and Count IV of American Needle's complaint are dismissed.

IT IS SO ORDERED.

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[2] The court notes that although a single, private correspondence is insufficient to find liability under the Lanham Act, commercial entities are not free to defame one another on an isolated basis with impunity. The Lanham Act did not abolish the common law torts of defamation, interference with contractual relationships, or interference with business expectancy or economic advantage, which, among others, could be used to redress any harm caused by a defamatory statement made outside the public-oriented realm of advertising and promotion.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Obukowicz

No. 91-2498

Decided October 30, 1992
Released April 23, 1993

PATENTS

1. Patentability/Validity — Obviousness — In general (§115.0901)

Examiner, in Patent and Trademark Office proceedings, bears burden of establishing prima facie case of obviousness based upon prior art, and examiner can satisfy this burden only by showing some objective teaching in prior art, or by showing that knowledge which is generally available to person of ordinary skill in art would lead that individual to combine references' relevant teachings.

2. Patentability/Validity — Obviousness — Relevant prior art — In general (§115.0903.01)

Prior art reference that gives only general guidance and is not at all specific as to particular form of claimed invention and how to achieve it may make certain approach "obvious to try" but does not make invention obvious.

3. Patentability/Validity — Specification — Enablement (§115.1105)

Examiner, in reviewing claims for combatting plant insect pests through utilizing plant-colonizing bacteria which have been genetically modified to produce protein toxin bacillus thuringiensis, correctly recognized that inventors' success with root-colonizing bacteria may not have been extrapolatable to bacteria colonizing leaves of plants and correctly challenged enablement from that viewpoint, but applicants have rebutted examiner's prima facie case of non-enablement.

Appeal from final rejection of claims (Richard C. Peet, primary examiner).

Application for patent filed June 7, 1989, by Mark G. Obukowicz, Frederick J. Perlak, and Lidia S. Watrud, serial no. 363,318, which is a continuation of application serial no. 799,369, filed Nov. 11, 1985, now abandoned; which is a continuation-in-part of application serial no. 728,906, filed April 30, 1985, now abandoned (plant-colonizing microorganisms containing the toxin gene b.

thuringiensis as a chromosomal insertion). From examiner's final rejection of claims 39-41 and 43-51, applicants appeal. Reversed.

Thomas P. McBride, of Rogers, Howell & Haferkamp; Larry R. Swaney, St. Louis, Mo., for appellants.

Before Goolkasian, Tarring, and W. Smith, examiners-in-chief.

Goolkasian, examiner-in-chief.

This is an appeal from the examiner's final rejection of claims 39 through 41 and 43 through 51. Claims 52 through 56, 58, 60 through 62, 64, 66 through 68, 70, 72 through 74, 76, 78 and 79 remain in the application but have been indicated as allowable by the examiner.

Claim 39 is illustrative of the invention and reads as follows:

39. A method of combatting plant insect pests which comprises applying to the plant environment or plant seed plant-colonizing bacteria having within its chromosome heterologous DNA encoding for the protein toxin of *Bacillus thuringiensis* which bacteria are capable of proliferating in the plant environment and which express an insecticidally effective amount of the protein toxin.

The references relied on by the examiner are:

McKay et al. (McKay), *Applied and Environmental Microbiology,* "Stabilization of Lactose Metabolism in *Streptococcus lactis* C2," Vol. 36, August 1978, pages 360-367.

Kloepper et al. (Kloepper), *Phytopathology,* "Development of a Powder Formulation of Rhizobacteria for Inoculation of Potato Seed Pieces," Vol. 71, 1981, pages 590-592.

Held et al. (Held), *Proceedings of the National Academy of Science, U.S.A,* "Cloning and localization of the lepidopteran protoxin gene of *Bacillus thuringiensis* subsp. *kurstaki,*" Vol. 79, October 1982, pages 6065-6069.

Simon et al. (Simon), *Bio/Technology,* "A Broad Host Range Mobilization System For *In Vivo* Genetic Engineering Transposon Mutagenesis In Gram Negative Bacteria," Vol. 1, November 1983, pages 784-791.

Weller, *Applied and Environmental Microbiology,* "Distribution of a Take-All Suppressive Strain of *Pseudomonas fluorescens* on Seminal Roots of Winter Wheat," Vol. 48, No. 4, October 1984, pages 897-899.

Dean, *Biotechnology and Genetic Engineering Reviews,* "Biochemical Genetics of the Bacterial Insect-Control Agent *Bacillus thuringiensis:* Basic Principles and Prospects for Genetic Engineering," Vol. 2, October 1984, pages 341-363.

Goldberg et al. (Goldberg), *Maximizing Gene Expression,* "The Selective Degradation of Abnormal Proteins in Bacteria," Chapter 9, W. Reznikoff and L. Gold (eds.), Butterworth Press, Boston, 1985, pages 287-314.

Kennell, *Maximizing Gene Expression,* "The Instability of Messenger RNA in Bacteria," Chapter 4, W. Reznikoff and L. Gold (eds.), Butterworth Press, Boston, 1985, pages 101-142.

Cullen et al. (Cullen), *TIBTECH,* "Biological control of leaf damage in plants," 1986, pages 115-119.

Lindow, *Microbiology of the phyllosphere,* "Strategies And Practice Of Biological Control Of Ice Nucleation-Active Bacteria On Plants," N. J. Fokkema and J. Van Den Heuvel (eds.), Cambridge University Press, Cambridge, 1986, pages 293-311.

Panopoulos, *Microbiology of the Phyllosphere,* "Tactics And Feasibility Of Genetic Engineering Of Biocontrol Agents," N. J. Fokkema and J. Van Den Heuvel (eds.), Cambridge University Press, Cambridge, 1986, pages 312-334.

Appellants' invention concerns a method of combatting plant insect pests utilizing plant colonizing bacteria which have been genetically modified to produce the protein toxin of *Bacillus thuringiensis.* The modification is accomplished by inserting DNA encoding for the protein toxin into the chromosome of the bacteria. The genetically modified bacteria are applied to the plant environment or the plant seed and express the insecticidally active protein toxin which is consumed by plant pests. This is said to control the growth and activity of the plant pests.

All of appellants' claims stand rejected under 35 U.S.C. § 112, first paragraph, as being broader than what is enabled by the specification's disclosure. The examiner is of the opinion that appellants' specification is "enabling only for claims limited in accordance with the as-filed specification" (Answer, page 4).

Appellants' claims also stand rejected under 35 U.S.C. § 103 over Dean in view of Held, Simon and McKay, and further in view of Weller or Kloepper, the latter two references being applied only with regard to claims 48 through 51.

We consider first the rejections under 35 U.S.C. § 103.

[1] In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki,* 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art *would lead* that individual to combine the relevant teachings of the references. *In re Fine,* 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Indeed, the teachings of references can be combined only if there is some suggestion or incentive to do so. *ACS Hospital Systems, Inc. v. Montefiore Hospital,* 723 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

It is the examiner's position that Dean suggests a method of combatting plant insect pests which comprises applying to the plant environment bacteria which is capable of survival and colonization in nature and harbors a gene encoding the toxin produced by *Bacillus thuringiensis.* It is further the examiner's position that the secondary references teach the advantages of and techniques for insertion of the *B. thuringiensis* toxin gene into the chromosome of the bacteria to stabilize expression of the gene.

We have carefully reviewed all of the references cited by the examiner in their entirety. We are unable to find a suggestion therein *to do* what appellants have done, namely incorporate the gene into the chromosome of a bacteria capable of proliferating in the plant environment and applying that bacteria to the environment or seed of the plant.

The Dean reference, though many pages long, is replete with advice regarding incorporation of the gene into plasmids of various bacteria, particularly, *E. coli,* but contains little information regarding how to use the transformed bacteria and clearly does not specifically suggest appellants' use. At page 357, Dean contains a short discussion of utility and suggests insertion of the gene into the plant itself to create a systemic and highly specific toxin. Dean also suggests increasing the amount of toxic per bacterial cell to lower the cost of conventional processes wherein the toxin itself is applied to the plant. Neither of these teachings is concerned with appellants' method of use. Dean also suggests the transfer of toxin genes "to other bacteria which have better survival in nature." Dean exemplifies this concept by noting that the mosquito-toxic bacteria *B. thuringiensis* var. *israelensis* survives only two days in nature and that other bacteria, such as "natural pond microflora," would make more suitable hosts.

[2] This specific statement regarding combatting mosquitos using genetically engineered "natural pond microflora" is relied on by the examiner for the "suggestion" required by the aforementioned case law. However, the specific statement by Dean is not a suggestion to insert the gene into the *chromosome* of bacteria *and* apply that bacteria to the plant environment in order to protect the plant. At best, the Dean statement is but an invitation to scientists to explore a new technology that seems a promising field of experimentation. The Dean statement is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it. Such a suggestion may make an approach "obvious to try" but it does not make the invention obvious. See *In re O'Farrell,* 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

The importance of a prior art suggestion's guidance as to *the particular form* of the invention may be dramatically illustrated by noting that the Dean comments regarding insertion of the gene into "other bacteria such as natural pond microflora" may well have been construed as referring to the entirely different approach of including the toxin gene in cyanobacteria, the bacteria that forms blue-green algae on pond surfaces. See *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991),[1] which discusses such an invention.

We recognize that given the teachings in appellants' specification regarding incorporation of the gene into the chromosome and utilizing the bacteria in the plant environment, one can theoretically explain the technological rationale for the claimed invention using selected teachings from the references. This approach, however, has been criticized by our reviewing court as hindsight reconstruction. See *In re Fine, supra,* 837 F.2d at 1075, 5 USPQ2d at 1600. See also *In re Sernaker,* 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

We consider next the rejection under 35 U.S.C. § 112. It is the examiner's position

[1] The title of the Vaeck patent application reads as follows: "Hybrid Genes Incorporating a DNA Fragment Containing a Gene [*B. t.*] Coding for an Insecticidal Protein, Plasmids, *Transformed Cyanobacteria Expressing Such Protein* and Method for Use as a Biocontrol Agent." (Inserts and emphasis added).

that appellants' disclosure is enabling only for claims limited in accordance with the "as-filed specification." The examiner is of the opinion that undue experimentation would be required to practice the invention particularly with regard to the development of host strains, transformation protocols and vectors for the insertion of toxin genes into the chromosomes of the vast number of heterogenous gram-positive and gram-negative bacteria encompassed by the claims. As explained by the examiner, difficulty would be encountered regarding identification and construction of host strains capable of expressing the gene without interfering with the ability of the strains to colonize the plant environment. The examiner notes that in the instant case there is not only unpredictability with regard to expression of any *B. thuringiensis* gene in the vast number of heterogenous bacteria encompassed by the claims but additional unpredictability in the use of any of the transformed bacteria in the claimed method of bio-control. In support of his position, the examiner has cited the literature articles by Lindow, Panopoulos and Cullen which discuss factors affecting the ability of bacteria to colonize plant tissue, and articles by Kennell and Goldberg which discuss the instability of mRNA in bacteria and the degradation of heterogenous proteins in bacteria.

Appellants, on the other hand, strongly urge the inapplicability of the literature articles to the facts of the instant case and provide declaration evidence by Dr. Douglas E. Berg. Dr. Berg is expert in the field of genetic engineering using the prokaryotic transposable element Tn5, the same transposon utilized by appellants.[2] Appellants also submitted the declaration of Dr. Pamela Marrone describing evaluations conducted utilizing leaf colonizing bacteria engineered to contain *B. t.* gene as described in the application. The declaration indicates that the bacteria *Pseudomonas putida*, a leaf colonizer, was engineered to express the gene coding for the *B. t.* toxin. The results of her work show that populations of the bacteria survived for as long as five weeks and that insect damage was less with the plants treated with transgenic bacteria. The data also showed that the engineered microorganism not only survived but proliferated to a stable population when the inoculum concentration of the population was initially low.

[2] A copy of Dr. Berg's review article, "The prokaryotic transposable element Tn5," which appeared in *Bio/Technology*, July 1983, is in the file.

We have carefully reviewed all of the references cited by the examiner, the Berg and Marrone declarations, the Berg article and, indeed, an article written by the examiner and referred to by Dr. Berg. We are of the opinion that any *prima facie* case of nonenablement established by the examiner has been overcome by the evidence submitted by appellants and, accordingly, we reverse the examiner's rejection.

We note specifically that Dr. Berg has supplied sound scientific reasoning in support of his position that the transposon strategy described in the application would have permitted many other plant colonizing bacteria to be transformed with *B. thuringiensis* gene. As noted by Dr. Berg, the inventors described the successful testing of four separate isolates of *Pseudomonas fluorescens* and two separate isolates of *Agro-bacterium radiobacter*. Transposition was obtained by the inventors utilizing a suicide plasmid. This appears to be the same approach utilized by the examiner and others to obtain transposition in *Pseudomonas syringae*. As noted in Dr. Berg's review article, the transposable elements are ubiquitous and have a characteristic ability to insert into many sites in the genomes of many host organisms.

Dr. Berg notes that most bacteria containing the gene would be expected to kill or impair the growth of insects in a plant environment. This is not an irrational statement considering the teachings of the Dean reference which indicate that the gene has been inserted into plasmids and introduced into several types of bacteria while retaining its capability of producing an active protein. Moreover, there is no indication that the gene caused the bacteria to alter its colonization behavior.

[3] We recognize that the inventors' success with root colonizing bacteria may not have been extrapolatable to bacteria colonizing the leaves of the plants. Accordingly, the examiner correctly challenged enablement from that viewpoint. In this case, however, appellants have submitted the Marrone declarations which show that the strain *Pseudomonas putida*, a naturally occurring nongenetically engineered leaf colonizing bacteria, was genetically engineered to contain the *B. t.* gene in the chromosome as claimed herein. That bacteria proliferated on the plants and expressed the protein toxin.

The examiner has not challenged the findings of Dr. Marrone other than to state that the tests were conducted *in vitro* under controlled environmental conditions in which the effects of the hostile plant environment (high temperature, osmotic stress, etc.) upon heterogeneous gene expression were not determined.

We recognize that Dr. Marrone's testing may well have been "*in vitro*" as compared to the growth of plants in open fields. We note, however, that this is a carefully regulated field of experimentation wherein there is great fear that the cloned trait may be undesirably mobilized into other types of bacteria in the field (appellant's specification, page 5, lines 30-33). As we understand it, the growth chamber test conducted by Dr. Marrone is a test customarily used for screening of plant related developments of potential utility in horticultural applications.[3] See *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980) regarding the use of "customarily used" screening tests for evaluation of utility of chemical compounds.

The issue of whether or not undue experimentation is required must be decided on the facts of each case. Reported cases are of limited precedential value. See, e.g., *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976); *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969). It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck, supra; In re Angstadt, supra* 537 F.2d at 502-03, 190 USPQ at 218. In the case before us, appellants' specification *literally describes* the plant-colonizing microorganisms which may be engineered as belonging to eight different genera, bacteria from the genus *Pseudomonas* being preferred. Moreover, the claims limit the microorganisms to those capable of colonizing the "plant environment," i.e., the surface of the plant, e.g., leaf, stem, buds, stalk, flower parts or root surface and the "rhizosphere" or soil which surrounds and which is influenced by the roots of the plant. The bacteria of the claims is also described as bacteria "capable of proliferating in the plant environment and which express an insecticidally effective amount of the protein toxin." The claims are not as broad as asserted by the examiner.

Appellants' declarations and the literature accompanying the Berg declaration indicate the ubiquity of the Tn5 transposon and substantiate the capability of one skilled in the art to prepare the claimed bacteria without undue experimentation. On the facts of this case, appellants have rebutted the examiner's *prima facie* case of non-enablement.

The examiner's rejections of claims 39 through 41 and 43 through 51 under 35 U.S.C. § 103 and 35 U.S.C. § 112 are reversed.

REVERSED.

[3] See also Watrud et al. (Watrud), "Cloning of the *Bacillus thuringiensis* subsp. *kurstaki* Delta-Endotoxin Gene into *Pseudomonas fluorescens:* Molecular Biology and Ecology of an Engineered Microbial Pesticide," which appeared in *Engineered Organisms in the Environment*, a cross disciplinary symposium June 10-13, 1935.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte D

No. 92-1168

Decided January 29, 1993
Released May 11, 1993

PATENTS

1. Patentability/Validity — Anticipation — Prior art (§115.0703)

Prior art patent is effective reference under 35 USC 102(e), even though some change was made between time application was filed and patent was published, since change in application disclosure does not per se constitute proscribed new matter, but rather issue is whether initial application adequately enabled person skilled in art to practice invention as claimed.

2. Patentability/Validity — Anticipation — Prior art (§115.0703)

Gene is chemical compound, albeit complex one, and thus prior decisions involving chemical compounds are applicable to claims involving DNA sequence coding for human tissue plasminogen activator.

Appeal from rejection of claims (N. Treptow, examiner, Richard A. Schwartz, supervisory primary examiner).

Application for patent filed by "D" [applicant's name and serial number have been redacted] (DNA sequence containing the DNA sequence coding for human tissue plasminogen activator originating from human normal cells, recombinant DNA incorporating the DNA sequence, host cells transformed with the recombinant DNA, and process for producing human tissue plasminogen activator by use of the host cells). From final rejection of claims 1 through 5, applicant appeals. Affirmed.

are of inferior quality and therefore the absence of this factor also supports the district court's determination.

8. Sophistication of the Buyers

Likelihood of confusion must be assessed by examining the level of sophistication of the relevant purchasers. *McGregor-Doniger Inc.*, 599 F.2d at 1137. Thus, we must consider "[t]he general impression of the ordinary purchaser, buying under the normally prevalent conditions of the market and giving the attention such purchasers usually give in buying that class of goods. . . ." *Id.* (quoting 3 R. Callmann, *The Law of Unfair Competition, Trademarks and Monopolies* § 81.2, at 577 (3d ed. 1969)).

Generally, purchasers of small items like lip balm are considered casual purchasers prone to impulse buying. *See RJR Foods, Inc. v. White Rock Corp.*, 603 F.2d 1058, 1061 [203 USPQ 401] (2d Cir. 1979). WWW's argument, however, rests on allegations of retailer confusion. Retailers are assumed to be more sophisticated buyers and thus less prone to confusion. *See Sally Gee, Inc. v. Myra Hogan, Inc.*, 699 F.2d 621, 626 [217 USPQ 658] (2d Cir. 1983). Thus, this factor also cuts against WWW.

[5] In light of all the factors discussed above, we conclude that WWW's Lanham Act claims must fail.[6] As noted by the district court,

> plaintiff's view of the reverse confusion doctrine is overly expansive. Plaintiff claims that the reverse confusion theory of liability prevents a larger, more successful defendant company from extensively promoting a similar mark in such a way that plaintiff's trademark is "swallowed-up, digested and destroyed for plaintiff's use." . . . However, where the parties are using similar marks on different products and where the balance of considerations ensures against a likelihood of confusion, the law does not give the plaintiff exclusive rights to usage of a particular trademark. As Judge Weinfeld has written, granting a plaintiff an injunction under such circumstances "would be tantamount to awarding it exclusive dominion over the use of the word, and the right to impair other parties' entrance into areas of endeavor far removed from its own. The trademark laws were not designed to serve this purpose."

W.W.W. Pharmaceutical Co., Inc., 1992 U.S. Dist. LEXIS at *37-38 (quoting *Information Clearing House, Inc. v. Find Magazine*, 492 F.Supp. 147, 163 [209 USPQ 936] (S.D.N.Y. 1980)).

Even were the *Polaroid* factors more in WWW's favor, equitable factors would weigh against granting it injunctive relief. Under the circumstances of this case, the injunction would greatly harm Gillette without giving WWW much benefit. In such cases, equitable relief is not warranted. *Lobo Enters., Inc. v. Tunnel, Inc.*, 693 F. Supp. 71, 79 n.4 [8 USPQ2d 1764] (S.D.N.Y. 1988).

B. State Law Claims

1. Unfair Competition

The state law cause of action for unfair competition shares many common elements with the Lanham Act claims of false designation of origin and trademark infringement, *Perfect Fit Indus., Inc. v. Acme Quilting Co., Inc.*, 484 F.Supp. 643, 646 [203 USPQ 481] (S.D.N.Y. 1979), *aff'd in part, rev'd in part*, 618 F.2d 950 [205 USPQ 297] (2d Cir. 1980), including proof of actual confusion to recover damages, *see Perfect Fit Industries, Inc.*, 618 F.2d at 955, and proof of a likelihood of confusion for equitable relief. *See id.* at 953 (citing cases). As demonstrated above, WWW has shown neither actual confusion nor a likelihood of confusion.

2. Dilution

WWW also seeks injunctive relief under New York's anti-dilution statute. N.Y. Gen. Bus. L. § 368-d (McKinney 1984).[7] A claim for dilution rests on the allegation that a defendant is attempting to "feed[ ] upon the business reputation of an established distinctive trade-mark or name." *Allied Maintenance Corp. v. Allied Mechanical Trades, Inc.*, 42 N.Y.2d 538, 545, 399 N.Y.S.2d 628, 632, 369 N.E.2d 1162, 1165 [198 USPQ 418] (1977).

[6] WWW's damage claim fails because in this circuit proof of real and precise actual consumer confusion is required to recover damages. *Coach Leatherware Co. v. AnnTaylor, Inc.*, 933 F.2d 162, 171 [18 USPQ2d 1907] (2d Cir. 1991). As no actual confusion has been demonstrated, WWW is not entitled to any monetary recovery.

[7] The statute provides as follows:

> Likelihood of injury to business reputation or of dilution of the distinctive quality of a mark or trade name shall be a ground for injunctive relief in cases of infringement of a mark registered or not registered or in cases of unfair competition, notwithstanding the absence of competition between the parties or the absence of confusion as to the source of goods or services.

Courts in this circuit have previously considered such claims, noting that:

> There are three elements of such a claim: (1) distinctiveness of the mark, either that the mark is "truly of distinctive quality" or has acquired secondary meaning in the eyes of the public; (2) likelihood of dilution, either as the result of blurring of product identification or the tarnishing of an affirmative association that a mark has come to convey; and (3) predatory intent. *Lobo Enters., Inc.*, 693 F.Supp. at 79 (quoting *Sally Gee, Inc.*, 699 F.2d at 625-26).

WWW has not put forth evidence to support any of the elements of a dilution claim. Even were the court to accept that WWW's mark is wellk-nown and has been subjected to dilution by Gillette's use of a similar mark, WWW has not shown any intent by Gillette to trade on WWW's reputation. *See Id.* at 79.

III. *CONCLUSION*

The judgment of the district court is affirmed.

Court of Appeals, Federal Circuit

Fiers v. Sugano

Nos. 92-1170, -1171

Decided January 19, 1993

PATENTS

1. Patentability/Validity — Date of invention — Conception (§115.0403)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Conception is question of law, reviewed de novo on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility.

PATENTS

2. Patentability/Validity — Date of invention — Conception (§115.0403)

Patent construction — Claims — Process (§125.1309)

Conception may occur if inventor is able to define DNA sequence by its method of preparation, but only if DNA is claimed by that method; conception of substance claimed per se, without reference to process, requires conception of its structure, name, formula, or definitive chemical or physical properties, and existence of workable method of preparation therefore cannot establish conception of subject matter of interference count in question, which is DNA sequence, having particular biological activity or function, claimed without reference to process.

3. Patentability/Validity — Specification — Written description (§115.1103)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Compliance with written description requirement of 35 USC 112 is question of fact, reviewed on appeal for clear error; interference party is entitled to benefit of earlier-filed foreign application only if specification satisfies description requirement by reasonably conveying to artisan that party had possession of claimed subject matter at time of application.

PATENTS

4. Practice and procedure in Patent and Trademark Office — Interference — Counts (§110.1703)

Patentability/Validity — Specification — Written description (§115.1103)

Specification containing statement that claimed DNA sequence is part of invention, and reference to potential method for isolating sequence, does not satisfy written description requirement of 35 USC 112, since specification does not describe DNA itself, nor even demonstrate that disclosed method would actually produce DNA in question, and since application therefore does not demonstrate that inventor had possession of claimed DNA; contention that correspondence between language of interference count and language in specification is sufficient to satisfy written description requirement is thus unpersuasive, since none of that

language particularly describes DNA sequence in interference.

5. Practice and procedure in Patent and Trademark Office — Interference — Counts (§110.1703)

Patentability/Validity — Date of invention — Conception (§115.0403)

Patentability/Validity — Specification — Written description (§115.1103)

Disclosure sufficient to satisfy written description requirement of 35 USC 112 for claimed DNA sequence must have same degree of specificity as disclosure which demonstrates conception, and must therefore include precise definition of DNA, such as by structure, formula, chemical name, or physical properties; interference count at issue, which purports to cover all DNA sequences that code for particular interferon, is analogous to single means claim, which has been held not to comply with Section 112, and thus language claiming all DNA sequences which achieve particular result, without defining what means will do so, is not in compliance with description requirement, even if language corresponds to that of count.

6. Patentability/Validity — Specification — Enablement (§115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Enablement is question of law that is reviewed de novo on appeal; enablement requirement of 35 USC 112 is satisfied if application contains description that enables one skilled in art to make and use claimed invention.

PATENTS

7. Practice and procedure in Patent and Trademark Office — Interference — In general (§110.1701)

Practice and procedure in Patent and Trademark Office — Interference — Burden of proof (§110.1707)

Patentability/Validity — Specification — Enablement (§115.1105)

Prevailing party in interference that did not produce extrinsic evidence of enablement did not, thereby, fail to prove that application is enabling, since party asserting failure to comply with 35 USC 112 bears burden of persuasion on that issue, and since prevailing party therefore had no further burden to submit extrinsic evidence of enablement once examiner accepted sufficiency of specification; opposing party was not deprived of opportunity to challenge prevailing party's entitlement to Japanese application filing date, even if opposer had no opportunity to cross-examine due to prevailing party's election to stand on filing date, since opposing party had other opportunities, including during motion period, to make such challenge.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Three-way patent interference proceeding (no. 101,096), between Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (application filed Oct. 27, 1980), Walter C. Fiers (application filed April 3, 1981), and Michel Revel and Pierre Tiollais (application filed Sept. 28, 1982). From decision awarding priority of invention (DNA which codes for a human fibroblast interferon-beta polypeptide) to Sugano, et al., Fiers and Revel, et al. appeal. Affirmed.

David J. Lee, James F. Haley, Jr., and Ivor R. Elrifi, of Fish & Neave, New York, N.Y.; Roger L. Browdy, of Browdy & Neimark, Washington, D.C., for appellants.

Nels T. Lippert, of White & Case, New York, for appellees.

Before Cowen, senior circuit judge, and Michel and Lourie, circuit judges.

Lourie, J.

Walter C. Fiers, Michel Revel, and Pierre Tiollais appeal from the June 5, 1991 decision of the Patent and Trademark Office Board of Patent Appeals and Interferences, awarding priority of invention in a three-way interference proceeding, No. 101,096, to Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (Sugano). We affirm.

BACKGROUND

This interference among three foreign inventive entities relates to the DNA [1] which codes for human fibroblast beta-interferon (β-IF), a protein that promotes viral resistance in human tissue. It involves a single count which reads:

> A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.

The parties filed U.S. patent applications as follows: Sugano on October 27, 1980, Fiers on April 3, 1981, and Revel and Tiollais (Revel) on September 28, 1982.[2] Sugano claimed the benefit of his March 19, 1980 Japanese filing date, Revel claimed the benefit of his November 21, 1979 Israeli filing date, and Fiers sought to establish priority under 35 U.S.C. § 102(g) based on prior conception coupled with diligence up to his British filing date on April 3, 1980.[3]

Sugano's Japanese application disclosed the complete nucleotide sequence of a DNA coding for β-IF and a method for isolating that DNA.[4] Revel's Israeli application disclosed a method for isolating a fragment of the DNA coding for β-IF as well as a method for isolating messenger RNA (mRNA) coding for β-IF, but did not disclose a complete DNA sequence coding for β-IF.[5] Fiers, who was working abroad, based his case for priority on an alleged conception either in September 1979 or in January 1980, when his ideas were brought into the United States, coupled with diligence toward a constructive reduction to practice on April 3, 1980, when he filed a British application disclosing the complete nucleotide sequence of a DNA coding for β-IF. According to Fiers, his conception of the DNA of the count occurred when two American scientists, Walter Gilbert and Phillip Sharp, to whom he revealed outside of the United States a proposed method for isolating DNA coding for β-IF, brought the protocol back to the United States.[6] Fiers submitted affidavits from Gilbert and Sharp averring that, based on Fiers' proposed protocol, one of ordinary skill in the art would have been able to isolate β-IF DNA without undue experimentation.[7] On February 26, 1980, Fiers' patent attorney brought into the United States a draft patent application disclosing Fiers' method, but not the nucleotide sequence for the DNA.

The Board awarded priority of invention to Sugano, concluding that (1) Sugano was entitled to the benefit of his March 19, 1980 Japanese filing date,[8] (2) Fiers was entitled to the benefit of his April 3, 1980 British filing date, but did not prove conception of the DNA of the count prior to that date, and (3) Revel was not entitled to the benefit of his November 21, 1979 Israeli filing date.

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[1] DNA is deoxyribonucleic acid, a generic term encompassing the many chemical materials that genetically control the structure and metabolism of living things.

[2] Revel assigned his application to Yeda Research and Dev. Co. Ltd. The real party in interest in the Fiers application has been indicated to be Biogen, Inc. The real party in interest in the Sugano application has been indicated to be Juridical Foundation, Japanese Foundation for Cancer Research.

[3] 35 U.S.C. § 102 provides in pertinent part:

> A person shall be entitled to a patent unless . . .
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

[4] Sugano's method involved the preparation of two populations of radioactivity-labelled cDNA probes prepared from the mRNA of fibroblast cells. One population of probes was prepared from the mRNA of induced fibroblast cells and the other population from the mRNA of non-induced cells. These probes were then exposed to a cDNA library prepared from induced cells, and the clones that only hybridized with the first probe were selected. The selected clones were then used as probes to select the full-length DNA sequence encoding β-IF, which was then sequenced.

[5] Revel's method involved preparing a cDNA library of clones from the mRNA of cells induced to produce β-IF, screening each clone for hybridization to mRNA from induced cells, eluting the hybridized mRNA, and assaying the eluted mRNAs for β-IF activity.

[6] Fiers presented his protocols and progress to date toward isolating DNA coding for β-IF at a September 21, 1979 meeting in Paris at which Sharp and Gilbert were present. Sharp and Gilbert returned to the United States on September 23 and 24, respectively. Fiers made a second presentation in Martinique on January 12, 1980. Gilbert and Sharp were both present and returned to the United States on January 15 and 17, respectively. On March 25, 1980, Fiers disclosed by telephone to his patent attorney that he had determined the entire nucleotide sequence of a DNA coding for β-IF. Fiers presented that nucleotide sequence along with a protocol for preparing the complete DNA in Switzerland on March 28, 1980. Fiers and his attorney worked from March 31 until April 2 in Ghent drafting the final portion and claims of the British application that Fiers filed on April 3, 1980.

[7] Fiers' proposed protocol involved preparing a cDNA library from the mRNA of cells induced to produce β-IF mRNA, and screening the cDNA library for a cDNA that, when introduced into a cell, would cause it to display β-IF activity.

[8] Sugano also claimed the benefit of an October 30, 1979 Japanese filing date which the Board denied. Sugano does not challenge that determination on appeal.

The Board based its conclusions on the disclosure or failure to disclose the complete nucleotide sequence of a DNA coding for β-IF.

DISCUSSION

Fiers' Case for Priority

The Board held that Fiers failed to establish conception in the United States prior to his April 3, 1980 British filing date. Specifically, the Board determined that Fiers' disclosure of a method for isolating the DNA of the count, along with expert testimony that his method would have enabled one of ordinary skill in the art to produce that DNA, did not establish conception, since "success was not assured or certain until the [β-IF] gene was in fact isolated and its sequence known." The Board relied on our opinion in *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), in which we addressed the requirements necessary to establish conception of a purified DNA sequence coding for a specific protein. Accordingly, the Board held that Fiers was entitled only to the benefit of his April 3, 1980 British application date because only that application disclosed the complete nucleotide sequence of the DNA coding for β-IF. That date was subsequent to Sugano's March 1980 Japanese priority date.

Fiers argues that the Board erroneously determined that *Amgen* controls this case. According to Fiers, the Board incorrectly interpreted *Amgen* as establishing a rule that a DNA coding for a protein cannot be conceived until one knows the nucleotide sequence of that DNA. Fiers argues that this court decided *Amgen* on its particular facts and that this case is distinguishable. Fiers' position is that we intended to limit *Amgen* to cases in which isolation of a DNA was attended by serious difficulties such as those confronting the scientists searching for the DNA coding for erythropoietin (EPO), *e.g.*, screening a genomic DNA library with fully degenerate probes. According to Fiers, his method could have been easily carried out by one of ordinary skill in the art.[*] Fiers also argues that *Amgen* held that a conception of a DNA can occur if one defines it by its method of preparation. Fiers suggests that the standard for proving conception of a DNA by its method of preparation is essentially the same as that for proving that the method is enabling. Fiers thus urges us to conclude that since his method was enabling for the DNA of the count, he conceived it in the United States when Gilbert and Sharp entered the country with the knowledge of, and detailed notes concerning, Fiers' process for obtaining it.

[1] Conception is a question of law that we review *de novo*. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81, 87 (Fed. Cir. 1986) (citing *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984)). Although *Amgen* was the first case in which we discussed conception of a DNA sequence coding for a specific protein, we were not writing on a clean slate. We stated:

> Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.

927 F.2d at 1206, 18 USPQ2d at 1021. We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.

[2] Fiers' attempt to distinguish *Amgen* therefore is incorrect. We also reject Fiers' argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognized that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

The present count is to a product, a DNA which codes for β-IF; it is a claim to a product having a particular biological activity or function, and in *Amgen*, we held that such a product is not conceived until one can define it other than by its biological activity or function. The difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans. While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity.

Fiers has devoted a considerable portion of his briefs to arguing that his method was enabling. The issue here, however, is conception of the DNA of the count, not enablement. Enablement concerns teaching one of ordinary skill in the art how to practice the claimed invention. *See* 35 U.S.C. § 112 (1988); *Amgen*, 927 F.2d at 1212, 18 USPQ2d at 1026. Since Fiers seeks to establish priority under section 102(g), the controlling issue here is whether he conceived a DNA coding for β-IF, not whether his method was enabling.

We conclude that the Board correctly decided that conception of the DNA of the count did not occur upon conception of a method for obtaining it. Fiers is entitled only to the benefit of his April 3, 1980 British filing date, since he did not conceive the DNA of the count under section 102(g) prior to that date.

Revel's Case for Priority

Revel bears the burden of proving entitlement to the benefit of his earlier-filed Israeli application date. *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1713 (Fed. Cir. 1988). To meet this burden, Revel must prove that his application meets the requirements of 35 U.S.C. § 112, first paragraph, *Bigham v. Godtfredsen*, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) (citing *Cross v. Iuzika*, 753 F.2d 1040, 1043, 224 USPQ 739, 741 (Fed. Cir. 1985)), which provides in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

Revel thus must show that the Israeli application contains a written description of the DNA of the count and that it is enabling.

The Board held that Revel's Israeli application did not contain a written description of a DNA coding for β-IF since it did not disclose the nucleotide sequence or "an intact complete gene." The Board, in denying Revel's request for reconsideration, rejected the argument that it is only necessary to show some correspondence between the language in the count and language in the Israeli application to satisfy the written description requirement. The Board stated:

> Moreover, what is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed. The test for sufficiency of support is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." As is apparent from our decision, we found the description in Revel's Israeli application inadequate to reasonably convey to the artisan that Revel was in possession of the invention of beta-interferon DNA [citations omitted].

Relying on *Amgen*, the Board concluded that the Israeli application was not enabling since Revel had not yet conceived the DNA of the count and "[l]ogically, one cannot . . . enable an invention that has not been conceived." Slip op. at 13.

Revel argues that the disclosure of his Israeli application satisfies the written description requirement because it contains language of similar scope and wording to that of the count. Revel cites the following passages from the Israeli application:

> The invention thus concerns also said purified m-RNAs which comprises normally up to 900-1000 nucleotides. . . . In the

[*] Fiers' method involved screening a cDNA library which he maintains is smaller and less complex than a genomic DNA library. Fiers also contends that his screening techniques were routine to those skilled in the art, while those skilled in the art lacked experience screening with fully degenerate probes. Fiers also notes that, in contrast to the situation with EPO in which erroneous amino acid sequence information had been published, the first thirteen amino acids of β-IF were known to the art.

same manner *it also concerns the corresponding c-DNA which can be obtained by transcription of said RNAs* [emphasis added];

It is a further object of the present invention to provide a process for the isolation of genetic material (DNA) containing the nucleotide sequence coding for interferon in human cells.

Revel points to a claim in the original Israeli application that corresponds substantially to the language of the count.[10] According to Revel, since the language of the count refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement. Revel thus urges that only similar language in the specification or original claims is necessary to satisfy the written description requirement.

[3] We disagree. Compliance with the written description requirement is a question of fact which we review for clear error. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *Utter*, 845 F.2d at 998, 6 USPQ2d at 1714. On reconsideration, the Board correctly set forth the legal standard for sufficiency of description: the specification of Revel's Israeli application must "reasonably convey[ ] to the artisan that the inventor had possession at that time of the . . . claimed subject matter." Slip op. at 3 (citing *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117).

[4] An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain *mRNA* coding for β-IF.[11] A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.

[5] As we stated in *Amgen* and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.

Because the count at issue purports to cover all DNAs that code for β-IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112. *See In re Hyatt*, 708 F.2d 712, 218 USPQ 195, 197 (Fed. Cir. 1983) ("the enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration.") Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.

The Board's determination that the Israeli application does not contain a written description of a DNA coding for β-IF was thus not clearly erroneous. The Board correctly determined that Revel is not entitled to the benefit of his November 1979 Israeli application since it fails to satisfy the written description requirement of section 112.[12]

Sugano's Case for Priority

The Board held that Sugano established entitlement to his March 19, 1980 Japanese filing date because the disclosure of his Japanese application contains the complete and correct sequence of the DNA which codes for β-IF, along with a detailed disclosure of the method used by Sugano to obtain that DNA. The Board rejected Fiers' argument that Sugano's March 1980 application is not enabling, since Fiers presented only attorney argument that was "unsupported by competent evidence, entitled to little or no weight and [was] unpersuasive in any event." Slip op. at 12.

Fiers argues that Sugano failed to prove that his application is enabling because he did not produce extrinsic evidence showing enablement. Fiers also argues that the Board erroneously imposed a burden on him to show that Sugano's application is not enabling when, in fact, Fiers had no right to submit rebuttal evidence once Sugano elected to rely solely on his Japanese application.

[6,7] Enablement is a question of law that we review *de novo*. *Amgen*, 927 F.2d at 1212, 18 USPQ2d at 1026. Enablement requires that the application " 'contain a description that enables one skilled in the art to make and use the claimed invention.' " *Id.*, (citing *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)). "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). "[A]ny party making the assertion that a U.S. patent specification or claims fails, for one reason or another, to comply with § 112 bears the burden of persuasion in showing said lack of compliance." *Weil v. Fritz*, 601 F.2d 551, 555, 202 USPQ 447, 450 (CCPA 1979). Thus, once the examiner accepted the sufficiency of Sugano's specification, Sugano had no further burden to prove by extrinsic evidence that his application was enabling; the Board correctly determined that it was Fiers (or Revel) who then had to prove that Sugano's application was not enabling. Even if Fiers had no opportunity to cross-examine Sugano because Sugano elected to stand on his filing date, Fiers had other opportunities, including during the motion period, to challenge Sugano's entitlement to his Japanese application filing date. Thus, he did not lack opportunity to challenge.

We conclude that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for β-IF and the Board did not err in determining that Fiers presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for β-IF and thus "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for β-IF]." *See Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117. The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of section 112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

CONCLUSION

The Board correctly awarded priority of invention to Sugano. Accordingly, the decision of the Board is

AFFIRMED.

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[10] Claim 22 of Revel's original Israeli application reads:

The DNA coding for a polypeptide having interferon activity insertable in a vector, such as plasmid PBR-322, and having up to 900-1000 nucleotides.

[11] According to Fiers, Revel's Israeli application also fails the written description requirement because the mRNA disclosed in the application encodes a protein weighing 23,000 daltons which is interleukin-6, not β-IF. The Board did not premise its decision on this point, and, since we determine that Revel's application does not describe the DNA of the count, we need not reach it either.

[12] In light of our disposition of the written description requirement question, we do not address whether Revel's Israeli application satisfies the enablement requirement.

District Court, D. Massachusetts

Enbee Plastics Inc. v. Heritage Albums Inc.

No. 91-30161-F

Decided October 26, 1992

PATENTS

1. Infringement — Tests (§120.09)

Patent owner's scientific study which compares strength and adhesive bond of declaratory judgment plaintiff's photograph pages with strength and adhesive bond of "Post-It" notes is of no relevance to whether plaintiff's adhesive exhibits pressure-sensitive qualities of kind and degree disclosed by patent in suit.

2. Infringement — Literal infringement (§120.05)

Summary judgment of non-infringement is warranted in declaratory judgment action brought by manufacturer of photograph album pages, in view of patent owner's failure to demonstrate triable issue of fact on issue of whether accused pages use pressure-sensitive adhesive as called for by patent in suit.

Particular patents — General and mechanical — Photo albums

4,702,026, Shaine, method of making pages for photo albums and pages thereby formed, declaratory judgment plaintiff's mo-